UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ALLYN TURNOFSKY, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

ELECTROCORE, INC., FRANCIS R.
AMATO, GLENN S. VRANIAK, BRIAN
POSNER, CARRIE S. COX, MICHAEL G.
ATIEH, JOSEPH P. ERRICO, NICHOLAS
COLUCCI, THOMAS J. ERRICO,
TREVOR J. MOODY, MICHAEL W.
ROSS, DAVID M. RUBIN, JAMES L.L.
TULLIS, STEPHEN L. ONDRA, CORE
VENTURES II, LLC, CORE VENTURES
IV, LLC, EVERCORE GROUP L.L.C.,
CANTOR FITZGERALD & CO., JMP
SECURITIES LLC, and BTIG, LLC,

Defendants.

Civil Action: 3:19-cv-18400-AET-TJB

JURY TRIAL DEMANDED

SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Court-appointed Lead Plaintiff Carole Tibbs ("Tibbs" or "Lead Plaintiff") brings this action on behalf of herself and all other persons or entities that: (i) purchased or otherwise acquired electroCore, Inc. ("electroCore" or the "Company") common stock pursuant and/or traceable to the Registration Statement (defined below) and Prospectus (defined below, and collectively with the Registration Statement and all amendments, the "Offering Documents") issued in connection with the Company's June 2018 initial public offering ("IPO" or the "Offering"); and/or (ii) purchased or otherwise acquired electroCore securities between June 22, 2018 and September 25, 2019, inclusive (the "Class Period"), subject to certain exclusions as described in ¶ 48 below (the "Class"). The claims asserted herein arise under (i) Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (the "Securities Act"), and (ii) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and United States Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder.

Lead Plaintiff's allegations are based upon personal knowledge as to herself and her own acts, and information and belief as to all other matters. Lead Plaintiff's information and belief is based upon, *inter alia*, the investigation conducted by and through her counsel, which included, among other things, a review and analysis of: (i) regulatory filings made by electroCore with the SEC; (ii) press releases, news articles, and other public statements issued by or concerning electroCore and the Individual Defendants (defined below); (iii) transcripts of investor calls with electroCore senior management; (iv) analysts' reports and advisories about the Company; (v) interviews with former employees of the Company; and (vi) other publicly available information. Counsel's investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within the custody or control of, Defendants

(defined below). Lead Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. <u>INTRODUCTION</u>

- 1. electroCore is a bioelectronic medicine company with a non-invasive vagus nerve stimulation ("VNS") therapy. Its sole product, gammaCore, is used for the acute treatment of pain associated with migraine and episodic cluster headache ("eCH") in adults. gammaCore devices are held alongside the patient's neck and are intended to lessen headache pain by providing electrical stimulation to the vagus nerve.
- 2. In June 2018, the Company went public, selling 5.98 million shares of common stock at a price of \$15.00 per share. The Company received net proceeds of approximately \$77.7 million from the Offering. The proceeds from the IPO were purportedly to be used to commercialize gammaCore products, expand the Company's clinical program into additional indications in headache and rheumatology, build its specialty distribution channel for the anticipated launch of gammaCore Sapphire, and for working capital and other corporate purposes.
- 3. As detailed herein, the Offering Documents were false and misleading and omitted to state material adverse facts. Critically, the Offering Documents misrepresented the type and size of electroCore's agreements that it had in place with "commercial payors" at the time of the Offering, and the number of lives covered or expected to be covered under those alleged agreements.
- 4. The Offering Documents stated, on page 2, under the title "Competitive Strengths," that at the time of the IPO,

Commercializing our therapy through traditional pharmaceutical channels. ... We have agreements in place with commercial payors that we believe, based on our estimates, will provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives with such number expected to

increase to as many as 45 million lives under these agreements over the next several calendar quarters.

- 5. The Offering Documents emphasized electroCore's alleged existing involvement with insurance reimbursement stating on page 4 under the title "Our Strategy," that:
 - "Drive reimbursement of our therapy. We are actively engaging with over 50 national and regional commercial insurance payors in the United States with the goal of securing reimbursement coverage as a pharmacy benefit. We have agreements with commercial payors in place that we believe, based on our estimates, will provide for reimbursement of gammaCore as a pharmacy benefit for approximately 17 million commercial lives, with such number expected to increase to as many as 45 million lives under these agreements over the next several calendar quarters.
- 6. The Offering Documents misleadingly discussed the terms "commercial payors," and "commercial insurance payors" in order to imply that the Company had agreements in place directly with commercial insurers such as Aetna or UnitedHealth. In fact, according to CW3 (discussed below), at the time of the IPO, there were no agreements directly with commercial insurance payers. Rather, electroCore had two limited agreements with pharmacy benefit managers ("PBMs") that gave the Company access to less than 10 million commercial lives, not to the 17 million as claimed above. PBMs are third party groups that act as a middleman between manufacturers and commercial payers, and manage certain payers' (health plans, large employers, unions and government entities) covered prescription lists, or formularies, and prescription benefits programs, and sometimes own their own pharmacy.
- 7. The Offering Documents also failed to disclose that the substantially larger of the two PBM agreements, with CVS Caremark ("CVS"), did not start reimbursements until the first quarter of 2019.
- 8. The Offering Documents also omitted key material adverse limitations in the PBM agreements and material adverse factors preventing further access to payer coverage and

reimbursement which resulted in significant cash outlays and accelerating cash burn leading to a massive restructuring and cost reduction plan less than one year after the IPO.

- 9. Importantly, among other things discussed below, the Offering Documents omitted the fact that at the time of the IPO gammaCore was not eligible for a Healthcare Common Procedure Coding System ("HCPCS") code or a National Drug Code ("NDC"), both of which would make it more difficult to reach agreements with commercial payers.
- 10. Lead Plaintiff asserts claims arising out of the false and misleading Offering Documents under Sections 11, 12(a)(2), and 15 of the Securities Act against electroCore, certain of its officers and directors, investment funds owned and controlled by certain of these officers and directors, and the underwriters of the IPO (collectively, the "Securities Act Defendants"). These Securities Act claims expressly exclude any allegations of scienter.
- 11. Lead Plaintiff also asserts claims arising under Sections 10(b) and 20(a) of the Exchange Act against the Exchange Act Defendants (defined below). As alleged herein, throughout the Class Period, the Exchange Act Defendants made materially false and/or misleading statements, and/or failed to disclose material facts, including, *inter alia*, that: (i) the type and size of third-party payer agreements purportedly in place were substantially different then represented; (ii) the PBM agreements included material adverse limitations on coverage and reimbursement; (iii) due to the uniqueness of gammaCore, the Company faced substantial undisclosed issues preventing payer coverage; (iv) electroCore's voucher program was harming the Company's negotiations with payers; and, (v) the foregoing would require significant cash outlays, accelerating cash burn and making the Company's purported business strategies unattainable.
- 12. Less than one year after the IPO, on May 14, 2019, electroCore announced first quarter 2019 financial results that fell short of investors' expectations, reporting \$410,000 net sales

and an operating loss of \$14.2 million with net cash burn for the quarter of \$16.2 million, and revealing certain restraints on its agreement with CVS limiting reimbursement for gammaCore, among other things. On this news, the Company's share price fell \$1.58, nearly 30%, to close at \$3.75 per share on May 15, 2019, on unusually heavy trading volume.

- 13. Just two weeks later, on May 29, 2019, the Company announced a drastic restructuring and cost reduction plan. On this news, electroCore's share price fell \$0.11, or over 5%, to close at \$1.95 per share on May 30, 2019, and continued to drop over the next two trading days, closing at \$1.65 per share on June 3, 2019.
- 14. Then, on August 13, 2019, electroCore announced a restructuring charge of \$850,000 in connection with the restructuring plan and expected quarterly cash burn exceeding \$7 million for some quarters. On this news, the Company's share price dropped over 10% from a closing price on August 13, 2019 of \$1.56 to a closing price of \$1.39 per share on August 14, 2019.
- 15. Finally, on September 25, 2019, the Company revealed that the U.S. Food and Drug Administration (the "FDA") had requested more information and analysis of clinical data for electroCore's 510(k) submission, which sought an expanded indication for the use of gammaCore for migraine prevention. On this news, the Company's share price fell \$0.79, over 23%, to close at \$2.57 per share on September 25, 2019, on unusually heavy trading volume.
- 16. By the commencement of this action, electroCore stock was trading as low as \$1.25 per share, a nearly 92% decline from the \$15.00 per share IPO price.

II. JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to (i) Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l(a)(2), and 77o), and (ii) Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

- 18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).
- 19. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). The Company's principal executive offices are located within this District.
- 20. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

A. <u>Lead Plaintiff</u>

21. Lead Plaintiff Tibbs, as set forth in her previously-filed certification (ECF No. 6-4) and incorporated by reference herein, purchased electroCore common stock directly in the IPO and pursuant and/or traceable to the Offering Documents and during the Class Period at artificially inflated prices and was damaged as a result of the federal securities law violations and false and/or misleading statements and material omissions alleged herein.

B. Defendants

- 22. Defendant electroCore is incorporated under the laws of the state of Delaware with its principal place of business located in Basking Ridge, New Jersey. The Company trades on the NASDAQ under the ticker symbol "ECOR."
- 23. Defendant Francis R. Amato ("Amato") served as the Company's Chief Executive Officer ("CEO") and member of the Board of Directors (the "Board") from July 2016 until September 30, 2019. Amato served as the Company's Chief Operating Officer ("COO") from July

2012 through July 2016. According to the Offering Documents, at the time of the IPO, Amato beneficially owned 1.5% of the total common stock of the Company. As of March 15, 2019, Amato beneficially owned 1.87% of the Company's common stock. Amato signed the Company's Registration Statement and electroCore's Form 10-K for the year ended December 31, 2018 (the "2018 Form 10-K").

- 24. Defendant Glenn S. Vraniak ("Vraniak") served as the Company's Chief Financial Officer ("CFO") from August 2016 until April 1, 2019. Vraniak signed the Company's Registration Statement and electroCore's 2018 Form 10-K.
- 25. Defendant Brian Posner ("Posner") has served as electroCore's CFO since April 1, 2019.
- 26. Defendant Joseph P. Errico ("J. Errico") served as the Company's Chief Science and Strategy Officer from July 2016 until May 31, 2019. J. Errico previously served as electroCore's CEO from January 2010 to July 2016. He co-founded electroCore with defendant Thomas J. Errico ("T. Errico") and non-party Peter S. Staats ("Staats"), has served as a member of the Board since 2005, and as Chairman of the Board from March 2013 until June 2018. According to the Offering Documents, at the time of the IPO, J. Errico beneficially owned 53.8% of the Company's common stock. J. Errico also serves as a Managing Director of defendants Core Ventures II, LLC ("CV II") and Core Ventures IV, LLC ("CV IV"), which in total owned 39.5% of the Company's common stock at the time of the IPO. As of March 15, 2019, J. Errico beneficially owned 39.72% of the outstanding shares of the Company. J. Errico signed or authorized the signing of the Company's Registration Statement. J. Errico also signed electroCore's 2018 Form 10-K.

- 27. Defendant Thomas J. Errico ("T. Errico") co-founded electroCore with J. Errico and Staats. T. Errico has served as a member of the Board since 2005. During the Class Period, T. Errico served as a member of the Board's Compensation Committee. According to the Offering Documents, at the time of the IPO, T. Errico beneficially owned 52.5% of the Company's common stock. T. Errico also serves as a Managing Director of defendants CV II and CV IV which in total owned 39.5% of the Company's common stock at the time of the IPO. As of March 15, 2019, T. Errico beneficially owned 38.41% of the outstanding shares of the Company. T. Errico signed or authorized the signing of the Company's Registration Statement. T. Errico also signed electroCore's 2018 Form 10-K.
- 28. Defendant Carrie S. Cox ("Cox") served as a director and Chairman of electroCore's Board from the time of the IPO until April 1, 2020. During the Class Period, Cox served on the Board's Audit Committee. Cox was identified in the Registration Statement with her consent as an individual who would assume service as a director of the Company upon the effectiveness of the Registration Statement. Cox also signed the Company's 2018 Form 10-K.
- 29. Defendant Michael G. Atieh ("Atieh") has served as a director of electroCore since the time of the IPO in June 2018. During the Class Period, Atieh served as the Chairman of the Board's Audit Committee. Atieh was identified in the Registration Statement with his consent as an individual who would assume service as a director of the Company upon the effectiveness of the Registration Statement. Atieh also signed the Company's 2018 Form 10-K.
- 30. Defendant Nicholas Colucci ("Colucci") served as a director of electroCore from August 2017 until June 2020. During the Class Period, Colucci served as Chairman of the Board's Compensation Committee. Colucci signed the Company's Registration Statement and electroCore's 2018 Form 10-K.

- 31. Defendant Trevor J. Moody ("Moody") has served as a director of electroCore since March 2013. During the Class Period, Moody served as a member of the Board's Compensation Committee. Moody signed the Company's Registration Statement and electroCore's 2018 Form 10-K.
- 32. Defendant Stephen L. Ondra ("Ondra") has served as a director of electroCore since the time of the IPO in June 2018. Ondra was identified in the Registration Statement with his consent as an individual who would assume service as a director of the Company upon the effectiveness of the Registration Statement. Ondra also signed the Company's 2018 Form 10-K.
- 33. Defendant Michael W. Ross ("Ross") served as a director of the Company from March 2018 until the completion of the IPO. Ross signed or authorized the signing of the Company's Registration Statement.
- 34. Defendant David M. Rubin ("Rubin") served as a director of the Company from March 2013 until the completion of the IPO. Rubin was designated as a director by stockholder Merck Global Health Innovation Fund ("GHI"), which owned 13.2% of the Company's common stock at the time of the IPO. Rubin signed or authorized the signing of the Company's Registration Statement.
- 35. Defendant James L.L. Tullis ("Tullis") served as a director of the Company from July 2014 until June 2020. During the Class Period, Tullis served on the Board's Audit Committee. According to the Offering Documents, at the time of the IPO, Tullis beneficially owned 1.1% of the total common stock of the Company. Tullis signed or authorized the signing of the Company's Registration Statement. Tullis also signed electroCore's 2018 Form 10-K.

- 36. Defendant CV II is a private equity investment firm based in Short Hills, New Jersey and is owned and controlled by defendants J. Errico and T. Errico. Immediately prior to the Offering, CV II owned 33.4% of the Company, and after the IPO, owned 26.7%.
- 37. Defendant CV IV is a private equity investment firm based in Short Hills, New Jersey and is owned and controlled by defendants J. Errico and T. Errico. Immediately prior to the Offering, CV IV owned 6.1% of the Company, and after the IPO, owned 4.9%.
- 38. Defendant Evercore Group L.L.C. ("Evercore") served as an underwriter and joint bookrunner in connection with electroCore's IPO. In the IPO, Evercore agreed to purchase 2,158,000 shares of the Company's common stock, exclusive of any over-allotment option.
- 39. Defendant Cantor Fitzgerald & Co. ("Cantor Fitzgerald") served as an underwriter and joint bookrunner in connection with electroCore's IPO. In the IPO, Cantor Fitzgerald agreed to purchase 1,430,000 shares of the Company's common stock, exclusive of any over-allotment option.
- 40. Defendant JMP Securities LLC ("JMP") served as an underwriter and joint bookrunner in connection with electroCore's IPO. In the IPO, JMP agreed to purchase 1,040,000 shares of the Company's common stock, exclusive of any over-allotment option.
- 41. Defendant BTIG, LLC ("BTIG") served as an underwriter and lead manager in connection with electroCore's IPO. In the IPO, BTIG agreed to purchase 572,000 shares of the Company's common stock, exclusive of any over-allotment option.
- 42. Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are sometimes referred to herein collectively, as the "Individual Defendants."
 - 43. CV II and CV IV are sometimes referred to herein as the "CV Defendants."

- 44. Evercore, Cantor Fitzgerald, JMP, and BTIG are sometimes referred to herein collectively, as the "Underwriter Defendants."
- 45. electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, the CV Defendants, and the Underwriter Defendants are sometimes referred to herein collectively, as the "Securities Act Defendants."
- 46. electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis are sometimes referred to herein collectively, as the "Exchange Act Defendants."
- 47. electroCore, the Individual Defendants, the CV Defendants, and the Underwriter Defendants are referred to collectively herein as "Defendants."

IV. <u>CLASS ACTION ALLEGATIONS</u>

- 48. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons or entities that: (i) purchased or otherwise acquired electroCore common stock pursuant and/or traceable to the Offering Documents issued in connection with the Company's June 2018 IPO; and/or (ii) purchased or otherwise acquired electroCore securities between June 22, 2018 and September 25, 2019, inclusive (the "Class Period"), and were damaged upon the revelation of the alleged corrective disclosures. Excluded are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns and any entity in which Defendants have or had a controlling interest.
- 49. Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, electroCore securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can be ascertained only through appropriate discovery, Lead Plaintiff believes that there are hundreds or thousands

of members in the proposed Class. Record owners and other Class members may be identified from records maintained by electroCore or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 50. Lead Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 51. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Lead Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 52. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
 - a. whether the Offering Documents contained any material misrepresentations or omissions;
 - b. whether Defendants have a viable good faith defense to the strict liability imposed by Section 11 of the Securities Act;
 - c. whether Defendants can establish negative causation as a defense to or as a reduction of the strict liability otherwise imposed by Section 11 of the Securities Act;
 - d. whether the Individual Defendants and/or the CV Defendants were control persons of electroCore for the purposes of Section 15 of the Securities Act and Section 20(a) of the Exchange Act;
 - e. whether the statements made by the Exchange Act Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of electroCore, or omitted facts necessary to make the statements not misleading;
 - f. whether the Exchange Act Defendants caused electroCore to issue false and misleading financial statements during the Class Period;

- g. whether the Exchange Act Defendants acted knowingly or recklessly in issuing false and misleading misrepresentations or omissions;
- h. whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether the prices of electroCore securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- j. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 53. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

V. BACKGROUND AND NATURE OF THE WRONGDOING

A. The Company and Its Business

- 54. electroCore was founded in 2005 as electroCore, LLC by defendant T. Errico, his nephew, defendant J. Errico, non-party Charles Theofilos, and non-party Staats. The Company is "a commercial-stage bioelectronic medicine company with a platform non-invasive vagus nerve stimulation therapy initially focused on neurology and rheumatology."
- 55. The Company was at all times extremely small, with only 64 employees at the time of the IPO, increasing to 91 full-time employees as of March 1, 2019. As of March 1, 2020, electroCore had 51 full-time employees.
- 56. electroCore's sole product is gammaCore, a "prescription-only vagus nerve stimulation, or VNS therapy administered in discrete doses using a proprietary" handheld delivery system. More specifically, the gammaCore device stimulates the vagus nerve, the longest cranial

nerve carrying signals from the digestive system to the brain, with "high-frequency burst waveform" (*i.e.*, electrical currents) which purportedly "has a measurable pharmacologic effect similar to several classes of medications." According to electroCore, prior to gammaCore, VNS "was only accessible to the most refractory patients, who were willing to endure surgery."

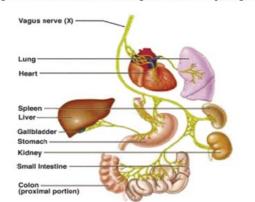


Figure 1: The distribution of the vagus nerve to multiple organs

57. The original gammaCore product was disposable and dispensed therapy on a 31-day prescription basis. Its successor, gammaCore Sapphire (pictured below), is rechargeable and reloadable, intended for multi-year use and activated on a monthly basis through the input of a unique, prescription-only authorization code, delivered via a radio-frequency identification ("RFID") card. At the time of electroCore's IPO, the U.S. commercial launch of gammaCore Sapphire was set to take place during the third quarter of 2018, with the original gammaCore product being phased out.



- 58. In April 2017, the FDA granted electroCore's *de novo* application, granting clearance for commercial sales of gammaCore for acute treatment of pain associated with eCH in adults. A *de novo* review is a regulatory pathway for products deemed to be low to moderate risk, but without an applicable predicate. gammaCore Sapphire was granted clearance by the FDA through the 510(k) pathway in December 2017.
- 59. Cluster headaches ("CH") are short extremely painful headaches described by patients and physicians as one of the most painful conditions in medicine. CH mainly affects males between 20 to 50 years of age with an "attack" lasting from fifteen minutes to three hours and the attacks clustering for two to twelve-week periods, followed by a remission period. The suicide rate among CH suffers is reportedly twenty times the U.S. national average, with the condition being sometimes referred to as the "suicide headache." According to electroCore, in the U.S., CH affects approximately 350,000 people (0.1% to 0.2% of the total population), with only about 225,000 people seeking treatment each year and with a total estimated market for treatment in 2018 of \$400 million. According to electroCore, prior to gammaCore, there was only one other FDA-approved CH treatment, injectable sumatriptan.

- 60. Given the small market for acute CH patients, it was vital for electroCore to expand into other markets. In January 2018, electroCore received FDA clearance for gammaCore's use for the acute treatment of pain associated with migraine in adults. According to the Company, there are approximately 36 million migraine sufferers in the U.S. with a total addressable market for acute treatment in 2018 of \$3.8 billion.
- 61. At the time of electroCore's IPO, it was in the process of pursuing additional label expansions for adolescent migraine, headache prevention indications, and the treatment of post-traumatic headache.

Preclinical / Commercial Pivotal FDA Indication Key Milestones Launch 1 Pilot Trials Trials Clearance Acute Treatment FDA clearance April '17 of Episodic Commercial registry initiated 3Q '17 Full commercial launch expected 3Q '18 Cluster Headache Acute Treatment · FDA label expansion January '18 of Migraine Full commercial launch espected 3Q '18 · Final PREMIUM trial data publication Migraine Prevention · 2nd pivotal trial initiation expected 2H '18 Migraine in Adolescents · Pivotal trial initiation expected 2H '18 Post-Traumatic Initial preclinical studies in progres Headache · Pilot trial initiation expected 2H '18

Table 1: Our Headache Pipeline

62. However, at the same time electroCore was gaining FDA clearance, several other competitors were also being granted FDA clearance for the same uses and/or entering the market. In fact, the FDA granted marketing approval for one such product as early as December 18, 2013. eNeura, Inc.'s ("eNeura") Cerena Transcranial Magnetic Stimulator (TMS) was the first FDA approved device to relieve pain caused by migraine headaches that are preceded by an aura. eNeura's next iteration of TMS, the SpringTMS, received 510(k) FDA clearance on May 23, 2014. SpringTMS is a prescription-only device that utilizes single-pulse Transcranial Magnetic

Stimulation to induce very mild electrical currents that can depolarize neurons in the brain and was the first medical device available to patients in the U.S. for the acute treatment of pain associated with migraine headache with an aura. On September 7, 2017, SpringTMS received 510(k) clearance from the FDA and was the only product in the U.S. indicated both for the acute and prophylactic (*i.e.*, prevention) treatment of migraine headache.

- 63. On March 12, 2014, the Cefaly Acute Medical Device was the first transcutaneous (passing through the skin) electrical nerve stimulation (TENS) device granted marketing approval by the FDA for use before the onset of a migraine, as a preventive treatment. On September 21, 2017, the FDA released the use of a new Cefaly medical device for the acute treatment of migraine, with or without aura. The Cefaly Acute allows migraine patients to use the device during a migraine attack, making the Cefaly medical technology more than just a preventive measure.
- 64. Another device, the Scion NeuroStim TNM (thermal vestibular stimulator), which is an in-ear prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of migraine headache, was also in the late stages of approval at the time of the Company's IPO. Its application was sent to the FDA on April 17, 2017, and it received FDA approval on March 26, 2018.
- 65. In addition to these medical devices that all represented potential competitors, a new category of drugs called calcitonin gene-related peptide ("CGRP") inhibitors either received FDA approval or were close to receiving FDA approval prior to the IPO.
- 66. For example, erenumab (Aimovig), the first FDA approved CGRP for the prevention of migraine in adults, received FDA approval on May 17, 2018. Prior to FDA approval, Amgen, Inc. (U.S.) ("Amgen") had submitted its Biologics License Application to the FDA on May 18, 2017, which the FDA accepted on July 20, 2017. On January 22, 2018, Novartis

International AG (rest of world) ("Novartis") announced that the drug met all primary and secondary endpoints in a unique phase IIIb study in episodic migraine patients who had failed multiple prior preventive treatments. Because several additional CGRP inhibitors would soon also be on the market, Amgen and Novartis priced the drug significantly below market expectations. Some analysts had anticipated the initial pricing to be as high as \$833 per month (\$10,000 per year), but the drug was priced at \$575 per month (\$6,900 per year), and with the "Aimovig Copay Program," a patient's out-of-pocket costs could be as little as \$5 per month.

- 67. Another drug, fremanezumab (Ajovy), received FDA approval on September 14, 2018, but Teva Pharmaceuticals submitted its Biologics License Application to the FDA on October 17, 2017. On December 18, 2017, the FDA accepted the application for priority review for the prevention of migraine and fast track review for the CH development program.
- 68. Similarly, galcanezumab (Emgality), which is for the preventative treatment of migraine, received FDA approval on September 27, 2018, but the FDA accepted its Biologics License Application on December 11, 2017.
- 69. As noted by confidential witness ("CW") 1, who spoke with doctors about trial result publications and provided medical education to the Company's sales staff, doctors even told CW1 that gammaCore sounded like something they were already prescribing and gave the example of Cefaly. According to CW1, based on publicized results, gammaCore "seemed comparable [in effectiveness] to other devices" including Cefaly. CW1 served as the Senior Director of Medical Affairs at electroCore from June 2018 to November 2018, and then Vice President ("VP") of Medical Affairs from November 2018 to June 2019 and was involved in overseeing the medical education provided by electroCore about the Company's products.

70. Facing the increasing competition for select markets, shortly after receiving the January 2018 acute migraine treatment clearance, on February 13, 2018, electroCore filed with the SEC a confidential draft registration statement on Form S-1, with its IPO officially announced in May of 2018.

B. <u>electroCore's Insurance Coverage Issues</u>

- 71. With one form of product income and facing intense emerging competition, including by companies with substantially more resources and experience such as Amgen, electroCore needed capital in order to commercialize gammaCore and thus went public in June of 2018.
- 72. In its Offering Documents and in later public filings, statements, and conference calls, electroCore and the other Defendants touted the Company's "commercial agreements" for coverage and reimbursement and access to millions of commercial lives, as well as business strategies that would permit electroCore to gain market share and increase sales of gammaCore.
- The type and size of third-party payer agreements purportedly in place were substantially different then represented; (ii) the PBM agreements included material adverse limitations on coverage and reimbursement; (iii) due to the uniqueness of gammaCore, the Company faced substantial undisclosed issues preventing payer coverage; (iv) electroCore's voucher program was harming the Company's negotiations with payers; and, (v) the foregoing would require significant cash outlays, accelerating cash burn and making the Company's purported business strategies unattainable.

- electroCore's Purported
 "Payer Agreements" Did Not Provide for Access to
 Million Lives and Contained Undisclosed Material Limitations
- 74. The Offering Documents and later Class Period statements asserted that the Company had "agreements in place with commercial payors that [electroCore] believe[s], based on [] estimates, will provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives[.]"
- 75. Prescriptions and medical devices like gammaCore can obtain "coverage and reimbursement" from various "payers" beyond the prescribed individual. These generally include commercial (*i.e.* publicly traded) and private insurance companies such as UnitedHealth, Aetna, and Blue Cross Blue Shield; integrated healthcare systems such as Kaiser Permanente and the Veterans Health Administration; government payers; and PBMs, who manage certain payers' covered prescription lists, or formularies, and prescription benefits programs, and sometimes own their own pharmacy. CVS is an example of one such PBM.
- 76. CW3 was employed with electroCore from April 2015 to January 2019 as VP of Payer and Provider Strategies, working remotely but also spending time at the Company's headquarters in Basking Ridge, New Jersey. CW3's *primary responsibility was to get managed care coverage for gammaCore*. In July 2016, CW3 began reporting to non-party Dan Duhart ("Duhart"), Global VP of Sales and Marketing and later Chief Commercial Officer, who reported directly to defendant Amato.
- 77. CW3 provided Amato and Duhart with regular updates on efforts to bring on commercial payers through telephone calls and occasionally in-person discussions at the Company's headquarters. CW3 stated that electroCore became intensely focused on trying to secure contracts as the Company went public in June 2018. "It's a prolonged process, which I'm not certain that everyone understood at the time. I don't believe they wanted to understand it.

They were determined that they were going public and once they did go public, they expected things to fall into place that weren't aligned to be in place at the time."

- 78. CW3 expounded on electroCore's assertion in the Offering Documents that it had agreements in place with commercial payers that would provide reimbursement for 17 million patients. According to CW3, at the time of the IPO, electroCore had agreements with two PBMs. One PBM agreement was small and limited and the main agreement, the agreement underlying the "17 million lives" claim, was with CVS.¹
- 79. CW3 explained that the Company originally thought gammaCore would be included in CVS's template formulary giving electroCore access to millions of patients, but later sometime in the beginning of 2018 received a "determination" from CVS and "when they told us what the contract really meant, [it] was significantly different than how we read it," stated CW3. Instead of access to millions of lives, gammaCore was not "on [CVS's] template formulary" and "at best" electroCore would have access to a "few million lives."
- 80. CW3 further clarified that while the Company's position was that the contract "applied to all of [CVS's] commercial lives," CVS's position was that if "somebody [one of CVS's managed care plans] comes to us and says 'We want to include this as a pharmacy benefit' then we would cover it for them. But they have to come to us. We're not promoting this.'"
- 81. Thus, electroCore knew that the CVS agreement would only cover "7 million [lives] *at most*." According to CW3, Amato and other senior executives definitely knew about the CVS agreement not covering nearly as many lives as initially thought, stating "[o]f course they knew that because they're trying to get people to buy stock in the company, so it was a big thing."

¹ The Offering Documents themselves confirm CW3's assertion that the CVS agreement was the basis for the "17 million lives" with an explanation that electroCore had an agreement with a PBM with access to 15 million lives.

- 82. In addition to the fact that the CVS agreement *did not* provide access to 15 million lives and the fact that CVS was not including gammaCore on its template formulary, there were numerous other material omissions regarding the CVS agreement. First, the CVS agreement *did not even commence reimbursement of gammaCore until the first quarter of 2019*, as later admitted by the Company. *See, e.g.*, ¶ 181 ("the CVS Caremark agreement [] will go into effect on January 1, 2019").
- 83. Even though the agreement was purportedly in effect as of January 1, 2019, CW7 noted that electroCore was "hoping to have things in place [with CVS] by the first quarter of 2019. And then what happened was they were still going back and forth; they still needed more information. And by the time I left in February [2019], I don't recall anything else happening." CW7, the Director of Clinical Affairs from April 2018 to February 2019, who worked out of the Company's headquarters and reported to Senior Vice President of Neurology Eric Liebler ("Liebler") who in turn reported to defendant Amato, was in charge of clinical studies, providing oversight to ensure electroCore complied with regulations and Company procedures. CW7 learned about potential agreements during regular monthly meetings that were attended by the Company's senior leaders, including defendants Amato and Vraniak.
- 84. CW5 also recalled the official partnership with CVS not being announced (at an all-hands meeting) until the first or second quarter of 2019. CW5 served as VP of Clinical Operations based out of the Company's headquarters from December 2018 to August 2019.
- 85. electroCore's first quarter 2019 earnings results showed minimal increase from the fourth quarter of 2018 with a mere \$42,000 increase in net sales compared to the fourth quarter of 2018 and Amato admitted that "our first quarter results do not fully reflect the positive impact of

new payers that were implemented during the quarter, including CVS Caremark" See ¶¶ 200-202.

- 86. Second, unbeknownst to investors until revealed on May 14, 2019, the CVS agreement further limited coverage by requiring that "the prescription [was] written by a neurologist and the patient has failed at least three other prescribed medications." *See* ¶ 202.
- 87. Third, the ability to obtain reimbursement under the CVS contract required extensive paperwork on behalf of the prescribing neurologist. *See* ¶ 202.
 - 2. electroCore Had No Direct Insurance Agreements for Coverage at the Time of the IPO or Throughout Most of the Class Period, Materially Affecting the Company's Sales
- 88. Not only was electroCore's purported access to "17 million lives" materially overstated at the time of the IPO, the Company had no direct insurance agreements in place with any insurance company, although the Offering Documents and later Class Period statements implied otherwise.
- 89. As stated in electroCore's Offering Documents, in order to "become and remain profitable" the Company had to "successfully commercialize [its] gammaCore therapy" which included "obtaining adequate coverage and reimbursement from payors[.]" In fact, as discussed herein, coverage by third party payers was, and continued to be throughout the Class Period, one of the most important drivers of the Company's success.
- 90. According to CW1, electroCore was not included on the formulary of any insurance company, explaining that a formulary is the list of drugs and services covered by an insurance company. As gammaCore was not on any formulary that meant it was not covered by any insurer.
- 91. CW3 stated that as of January 2019, electroCore did not have any agreements in place with insurance companies, stating "there were no payers that were covering [gammaCore], like United or Aetna or anything like that. No, they had no coverage at that time."

- 92. CW3 added that defendants Amato, Posner, Vraniak, J. Errico, Cox and Ondra would all have known there were no insurance agreements in place. Furthermore, CW3 recalled CW3's replacement stating "I told the Board how it is. No, we don't have any coverage."
- 93. CW3 also stated that in discussions with commercial payers, the main concern was that electroCore's ACT 1 and ACT 2 trials for gammaCore did not meet the primary endpoint for patients with eCH. "They all mentioned the studies that were done, what was wrong with the studies. None of the studies had hit their primary endpoints." CW3 said the commercial payers also had concerns over the small size of the studies and the small population of potential patients who would need gammaCore. "The payers said, 'We don't really need this.""
- 94. CW4, a Strategic Business Consultant with electroCore from January 2015 to September 2018 who helped manage the data from the RFID cards used with the device and reported to Duhart and defendant Vraniak, stated: "They went public before they had any payers on board. I don't think anyone was going to pay \$500 [to use gammaCore]." CW4 added, "I think they probably should have gotten some coverage as medical coverage, but they were trying to do it as a pharmacy benefit."
- 95. CW5 noted that in May 2019, electroCore laid off almost half of its workforce, forcing the Company to stop work on some clinical trials. CW5 stated that the Company blamed the workforce reduction on the lack of funding due to the slow "uptake" of gammaCore by insurance companies. "They hadn't received approvals for their device. They kept blaming it on the uptake with the insurance companies and not getting coverage for the device as quickly as expected."
- 96. CW5 recalled discussions regarding the Company's efforts to reach agreements with insurance companies during senior manager meetings that took place twice a month and

explained that insurance companies only provide limited time periods during each year when companies like electroCore could reach agreements with them. CW5 stated that if the window of opportunity was missed, a company would have to wait until the following year's negotiation window, "[i]t's not like with an oncology drug where you get the attention of the insurance companies right away."

- 97. When asked why the Company struggled with insurance companies, CW5 stated that electroCore was still trying to figure out the best patient profile that would benefit from using gammaCore. CW5 went on to explain that some data suggested that patients with migraine with accompanying sensory disturbances ("aura" headaches) would benefit more but that was a small subset of the migraine population and it was a challenge to find additional subsets of patients who would benefit from gammaCore.
- 98. CW6 echoed the sentiments of the other confidential witnesses. CW6 worked as a Senior Territory Business Manager for electroCore from May 2018 to April 2019, meeting with doctors in the field in hopes of getting them to prescribe gammaCore. CW6 reported to the Regional Business Director who in turn reported to Duhart and defendant Amato. CW6 stated that the problem was that *no agreements had been reached with insurers and the device was not listed on any formularies*, "[t]hat was probably the demise."
- 99. CW6 also recalled that Duhart led quarterly national sales conference calls during which he would provide updates on the Company's efforts to reach agreements with insurance companies. "It was the same message every time we would be on national conference calls. 'We're still trying. We're real close.' That was pretty much it." In summation, CW6 stated, "It doesn't take a rocket scientist to figure out that you can't keep giving away products and not getting

coverage for it. We all knew that if we didn't get coverage, if there's no coverage, the company's not going to be able to sustain."

- 100. CW7 also stated that during CW7's tenure there were no agreements in place with any commercial insurance companies to cover gammaCore. As of February 2019,² "[t]hey were working on a few," stated CW7, but "[b]y the time I left, there was nothing signed on the dotted line."
- July 2019, working remotely and in the Company's headquarters office and reporting to Duhart and then the VP of Payer and Provider Strategies who both reported to Amato. CW8 wrote and presented contracts to potential payers. According to CW8, other than the agreement with CVS (*see* Section V.B.1. above), electroCore had not finalized any agreements with commercial payers to cover gammaCore during CW8's tenure.
- 102. CW9 worked for the Company in the headquarters office from January 2019 to May 2019 as Coordinator Quality Assurance and Regulatory Affairs. "From what [CW9 understood], part of the reason why [CW9 and almost half of the employees] got let go is because [electroCore was] promised that the insurance company was going to cover [gammaCore] and then it didn't end up happening."
- 103. The lack of insurance agreements was a significant impediment to electroCore's success. As several CWs noted, without insurance coverage, medical professionals did not want to prescribe gammaCore to their patients. For example, CW6 stated that about 80% of the doctors CW6 met with who wanted to prescribe gammaCore would not write a prescription for it unless it

² CW7's tenure ended in February 2019. A February 26, 2019, Company press release announced "positive coverage polices" for gammaCore by Highmark who serves over 5 million patients according to the press release.

was covered by insurance. Some doctors would take the extra steps of submitting letters on behalf of their patients and insurers would cover the cost of gammaCore about 10% of the time in those cases.

- 104. CW6 also commented that CW6 and other sales representatives repeatedly told Duhart and other management that, "We have doctors that do want to prescribe [gammaCore], but their patients can't afford \$500 a month. That was a broken record."
- 105. CW1 stated that "[t]he biggest issue [CW1] would hear after [] describing the science of the product is they would say 'I would like to prescribe this. I wish it was covered by the insurance companies." According to CW1, there were concerns about the cost to patients since gammaCore was not covered by insurance, meaning patients would have to pay out of pocket, participate in a payment plan, or use a "voucher program," where electroCore would allow patients to use the device for free for one month. CW1 also heard from members of the sales department during CW1's tenure that the sales staff experienced pushback in marketing gammaCore because it was not covered by insurers.
- 106. CW2 echoed CW1's physician findings, stating that pricing was the top concern expressed by physicians. CW2 added that physicians had concerns with gammaCore's 20% placebo rate. CW2 served as the Medical Science Liaison at electroCore from October 2017 to June 2019, reporting to the VP of Medical Affairs and conveying the science behind gammaCore to physicians, researchers, prescribers, insurance providers, and any other group that requested information about gammaCore. CW2 covered about one-half of the country and traveled regularly to give clinical presentations about gammaCore and the clinical trials. CW2 gave weekly updates to the VP of Medical Affairs about the groups and people spoken to and relayed any new insights, questions, or concerns raised with CW2.

107. CW10, employed as a Senior Territory Business Manager from April 2018 to May 2019 who called doctors and asked them to prescribe gammaCore, also commented that doctors raised concerns about getting insurance to cover the cost of the device, stating "You've got to have coverage. People just don't have extra cash laying around."

3. Additional Material Barriers Hindered electroCore's Ability to Enter into Agreements with Insurers

- 108. electroCore's sales at the time of the Offering and throughout the Class Period suffered immensely due to the fact that third-party payers would not reimburse or cover gammaCore, and although not disclosed to investors, one of the prime reasons for the lack of coverage was the fact that gammaCore was not eligible for an HCPCS code.
- 109. At the time of the IPO, according to CW3, gammaCore was not eligible for an HCPCS code or a NDC, both of which would make it more difficult to reach agreements with commercial payers.
- 110. CW3 went on to explain that "[t]he problem [was] that [the HCPCS] codes are only issued once a year. So you have to have your request for a code submitted before January 2020 to get a code effective [for] 2021. It takes a year for a code to be issued." gammaCore failed to meet the requirements for an HCPCS E-Code (code for durable medical devices) and could not receive the E-Code classification because of the durability of the device. The first device was disposable and gammaCore Sapphire depends on a disposable RFID card and therefore is not eligible for E-Code classification.
- 111. CW3 further explained that to obviate the cumbersome coding process for medical devices, electroCore wanted to secure reimbursement as a pharmacy benefit³ as opposed to a

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³ This lack of ability to secure reimbursement as a pharmacy benefit was a second major undisclosed issue that impeded sales with doctors reticent to prescribe as no insurance companies would cover gammaCore as a pharmacy benefit. See ¶¶ 88-107 above (CWs discussing this issue).

medical benefit. First, the way many payers were licensed they were required to cover durable medical equipment (such as gammaCore) as a medical benefit not a pharmacy benefit, said CW3.

- 112. Second, given that gammaCore is not a drug, it did not receive a NDC from the FDA and instead had to file to receive a unique identifier from the National Council for Prescription Drug Programs. CW3 stated that the issue with this was that First Databank, Inc. ("First Databank"), the largest database used by commercial payers, does not list non-drug NDCs along with its drug codes and instead has a unique database for devices that must be purchased separately. "So, you would have a payer who said, 'We'd like to cover [gammaCore], but we can't find it in the database."
- about the fact that gammaCore was not eligible for the HCPCS code and that it may not be eligible for the E-Code for durable medical equipment, but the information about code eligibility was later removed. CW3 discussed the issue with Amato and Duhart during in-person meetings at electroCore's headquarters in late winter/early spring 2018, telling them that the code eligibility issue should be mentioned in the Registration Statement. CW3 also brought the issue up at a dinner with Amato and Duhart in October 2018.
- 114. CW3 added, "I think that they didn't provide investors with all the information they had and knew and had available to them when they filled out the S-1 document." "My belief was that in the S-1 document, electroCore should have stated that they were aware that gammaCore may not fit the definition of Durable Medical Equipment, which would mean it may not be eligible for a unique E-Code under the HCPC system. And that, in my estimation, *I thought that was extremely important to people who were going to invest in the company*, and it was just ignored, completely ignored."

- the Company's own post-Class Period statements belie the extreme importance of obtaining an HCPSC code. Between August 13, 2020 and July 13, 2021, electroCore discussed the HCPCS code in no less eleven public statements, and after receiving one repeatedly touted it as "a major U.S. reimbursement milestone." A press release issued on January 19, 2021, is wholly dedicated to the issue, titled "electroCore, Inc. Announces the Establishment of a Unique Level II HCPCS Code for 'Non-Invasive Vagus Nerve Stimulator'" which announced the coding decision by the Centers for Medicare and Medicaid Services ("CMS") to give gammaCore a unique coding number, but not an E-Code, confirming CW3's statements regarding ineligibility for such a code. Notably, in order to finally be eligible for such a code, electroCore had to first create a version of gammaCore that provisioned for 36 months of therapy to meet the CMS definition of durable medical equipment as opposed to earlier generations of the product that only provided for one to three months of therapy.
- 116. In addition to the undisclosed code issues and related pharmacy benefit issue (and thus doctor reticence to prescribe), Defendants failed to disclose that the Company's voucher program was changed in manner that actually harmed gammaCore sales.
- 117. CW3 stated that electroCore knew it needed to demonstrate demand for gammaCore in its efforts to secure coverage, and initially gave patients a one- or two-month free trial of the device by having doctors submit prescriptions, which created a record of the request that the Company could show to potential payers. gammaCore was sent to the dispensing pharmacy which would then bill the payer and ship the device to the patient and if the prescription request was denied, electroCore would pay the pharmacy for the device. "What we wanted to do was for the doctor to submit the prescription so there would be a record of a request for a patient

to [use gammaCore]. And in that way, we would demonstrate [to payers] that we were creating demand."

- 118. CW3 explained that the process changed in March or April of 2018 when Duhart initiated the voucher program wherein patients received the device free of charge for one to two months, bypassing commercial payers entirely. "The doctor wrote the prescription, the prescription went into our people who were doing distribution at Asembia, and they would ship the device. But the payer never saw that because you were giving them a free device." CW3 continued, "When we changed to the voucher program, all that happened was a dispensing pharmacy sent a device to a patient, but the insurance company was never billed. So now you haven't created any demand." CW3 added, "[electroCore] gave away a hell of a lot of gammaCore but you didn't end up with any payers covering it."
- determine pricing "backward" and explaining that it was initially priced at \$299 then maybe \$399, and then when Duhart was hired, raised to \$575. "With no market input, no focus groups, no payer strategy groups, none of that. It was really done backward. 'How much money will we need in order to have a successful IPO?' They worked the pricing of it backward." CW3 added that since the patient pays for the device even if they do not have headaches, "[i]t was more like a subscription than a prescription."

C. Defendants Had Advance Warning that Additional Use Clearance Would Likely Be Delayed

120. Not only did the Offering Documents and Class Period statements misrepresent and fail disclose material adverse payer coverage issues, the Exchange Act Defendants also failed to disclose material issues with the FDA clearance process in the Company's late Class Period public statements.

- 121. electroCore was seeking additional use clearances for gammaCore during the Class Period. Most immediate was clearance for use in migraine prevention.
- 122. CW5 commented on the FDA process, stating that it was "odd" that Liebler was the primary FDA contact when most companies CW5 previously had worked for had a Regulatory Affairs employee versus someone from Clinical. Based on CW5's conversations with Liebler, the FDA had raised concerns about the robustness of electroCore's data to support the use of gammaCore for migraine prevention.

VI. VIOLATIONS OF SECTIONS 11, 12(a)(2), AND 15 OF THE SECURITIES ACT

- 123. For all claims stated within this Section VI., Lead Plaintiff expressly disclaims any allegations that could be construed as alleging fraud or intentional or reckless misconduct.
- 124. The Securities Act claims are brought against the following defendants: electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, the CV Defendants, and the Underwriter Defendants, *i.e.*, the Securities Act Defendants.
- 125. Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis each participated in the preparation of and signed (or authorized the signing of) the Registration Statement and/or an amendment thereto, and the issuance thereof.
- 126. Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are strictly liable for the materially untrue and misleading statements incorporated into the Offering Documents. By virtue of their positions with the Company, they possessed the power and authority to control the contents of electroCore's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and market investors.

- 127. In the run-up to the IPO, the Underwriter Defendants: (i) assisted in the preparation and presentation of any "road show" materials designed to induce investment in the Company; (ii) conducted due diligence on the Company, including, *inter alia*, access to confidential corporate information concerning electroCore's business operations unknown to the investing public; and (iii) consulted with Company management regarding the content of the Offering Documents.
- 128. Pursuant to the Securities Act, the Underwriter Defendants are liable for the materially untrue and misleading statements in the Offering Documents. The Underwriter Defendants assisted electroCore and certain Individual Defendants in planning the IPO and were required to conduct an adequate and reasonable investigation into the business and operations of electroCore to participate in the IPO a process known as a "due diligence" investigation. During the course of their due diligence investigation, the Underwriter Defendants had continual access to confidential corporate information concerning electroCore's operations and financial prospects.
- 129. In addition to availing themselves of virtually unlimited access to internal corporate documents, agents of the Underwriter Defendants met with electroCore's lawyers, management, and top executives and made joint decisions regarding: (i) the terms of the IPO, including the price at which electroCore shares would be sold to the public; (ii) the strategy to best accomplish the IPO; (iii) the information to be included in the Offering Documents and other offering materials; and (iv) what responses would be made to the SEC in connection with its review of the Offering Documents.

A. electroCore's Initial Public Offering

130. electroCore filed its initial confidential draft registration statement on Form DRS with the SEC on February 13, 2018. Amended Forms DRS were then filed on April 2, 2018 and May 11, 2018, with the first registration statement on Form S-1 filed with the SEC on May 21, 2018. electroCore filed amendments to the Form S-1 on June 5, 2018, June 11, 2018, and June

15, 2018 (collectively, the "Registration Statement"). The Registration Statement was declared effective by the SEC on June 21, 2018.

- 131. On June 25, 2018, electroCore filed with the SEC a prospectus pursuant to Rule 424(b)(4) (the "Prospectus"), commencing its IPO of 5.2 million shares of common stock at a price of \$15.00 per share. The Offering Documents stated that the intended use of the IPO proceeds was to be as follows: (i) \$35 million to fund commercialization of products; (ii) \$10 million to fund expansion of its clinical programs; (iii) \$3 million to fund the build out of a specialty distribution channel for the launch of gammaCore Sapphire in the third quarter of 2018; and (iv) the remaining balance for working capital and other corporate purposes.
- 132. On June 28, 2018, electroCore announced that the Underwriter Defendants had chosen to exercise their option to sell an additional 780,000 shares. In total, electroCore issued and sold 5,980,000 shares of common stock, reaping net proceeds of approximately \$77.7 million.

B. Defendants Used Material Misstatements and Omissions in the Offering Documents to Sell electroCore Stock to the Investing Public

- 133. electroCore's IPO garnered the Company net proceeds of over \$77.7 million and permitted the Company to continue to operate. Unbeknownst to Lead Plaintiff and the Class, the Offering Documents were negligently prepared, containing numerous materially false and misleading statements and omitting material adverse facts.
- 134. The Offering Documents stressed and repeated no less than six times that electroCore had agreements in place with commercial payers providing for reimbursement of gammaCore as a pharmacy benefit and giving the Company access to 17 million lives at the time of the IPO with access of up to 45 million lives expected in the near future, when as discussed extensively above, the Company had no direct agreements with commercial insurance company and only two limited agreements with PBM's. *See* quoted paragraphs 4 and 5 above.

135. The Offering Documents explained under a section titled "Coverage and Reimbursement" the following:

While some commercial payors may provide coverage under their pharmacy benefit plans, other payors, including governmental and private insurers, may not be willing or authorized to provide coverage for our therapy under pharmacy plans that more commonly cover prescription drug products. These payors may require us to seek coverage for gammaCore as a medical supply or item of durable medical equipment, which could result in the application of different pricing, reimbursement, and patient cost-sharing policies to our products.

- 136. The above Offering Documents statements in ¶¶ 134-35, were materially false and/or misleading and omitted to disclose material information necessary to make the statements not misleading. Specifically, the Offering Documents:
 - (i) misrepresented the type of agreements electroCore had in place at the time of the Offering, stating no less than six times that agreements were in place with "commercial payors" when the Company only had agreements with PBMs and no insurance companies (see ¶ 74-107);
 - (ii) misrepresented the number of commercial lives that the Company had access to, stating that at the time of the Offering there was access to "approximately 17 million lives" with one of the agreements making up 15 million of those lives, when in fact that agreement provided for 7 million lives *at most* (*see* ¶¶ 78-81);
 - (iii) misrepresented that access to 15 to 17 million lives was current when in fact CVS would not begin reimbursement until over six months later, during the first quarter of 2019 (see ¶¶ 82-85);
 - (iv) omitted key material adverse limitations for the purported "commercial payor" agreements, failing to disclose that gammaCore would not be included on CVS's template formulary and that in order for the coverage to apply, the prescription had

- to be written by a neurologist and the patient had to have failed with at least three other prescribed medications ($see \P 79-80, 86-87$);
- (v) omitted key material adverse factors preventing access to payer coverage and reimbursement and subsequently materially harming sales of gammaCore and electroCore's financial results, including:
 - that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment, needing to create a new gammaCore product version in order to receive the code (*see* ¶ 110, 113-15);
 - that in order to be covered as a pharmacy benefit, gammaCore needed a drug code, but because it was not a traditional drug could not receive one and the largest database used by commercial payers, First Databank, did not list non-drug NDCs along with its drug codes and needed to develop a third database for codes like gammaCore, something that was not even developed until 2019 and not available until 2020 (see ¶¶ 111-12);
 - that the voucher program changes in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18);
 - (d) that as a result of the above, the Company would struggle to obtain agreements with payers for coverage and reimbursement; and,

- that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage (see ¶¶ 95, 99, 102-107); and
- (vi) as a result of the foregoing, failed to disclose that all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable; and
- (vii) as a result of the foregoing, the positive statements about electroCore's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.
- 137. The Offering Documents risk disclosures, including the section titled "Risks Associated with Our Business," do not contradict the misrepresentations or omissions set forth above. Instead, they speak of vague future contingencies and risks regarding the possibility that that third party payers may not agree to cover gammaCore. The disclosures, however, continue to misrepresent or omit material present facts regarding existing coverage, and specific known risks of obtaining future coverage.
 - 138. Specifically, the Offering Documents risk disclosures:
 - (i) omitted that physicians and payers did not find the clinical data compelling at the time of the Offering ($see \P 93, 97, 106$);

- omitted that there were then-existing substantial issues preventing payer coverage not only for gammaCore as a pharmacy benefit, but also as medical device and thus commercialization of gammaCore was *already* being negatively affected, including:
 - that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment (*see* ¶¶ 110, 113-15);
 - that in order to be covered as a pharmacy benefit, gammaCore needed a drug code, but because it was not a traditional drug could not receive one and the largest database used by commercial payers, First Databank, did not list non-drug NDCs along with its drug codes and needed to develop a third database for codes like gammaCore, something that was not even developed until 2019 and not available until 2020 (see ¶¶ 111-12);
 - (c) that the voucher program changes in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18); and,
 - (e) that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel

had to spend substantial time assisting physicians with the paperwork and following up on coverage (see ¶¶ 95, 99, 102-107).

- 139. As a result of the foregoing, the disclosed risks were not a mere possibility, a "may" or "could" occur, but were in fact occurring and would lead to modification of the Company's commercialization strategy and have a material adverse effect on the sales of gammaCore and the Company's results of operations.
- 140. The Offering Documents were also materially untrue and misleading because they failed to meet the requirements of Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(3)(ii). Item 303 requires issuers to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results.
- 141. Similarly, Item 503(c) of SEC Regulation S-K, 17 C.F.R. § 229.503(c),⁴ required, in the "Risk Factors" section of the Offering Documents, a discussion of the most *significant factors* that make the Offering risky or speculative and *that each risk factor adequately describe the risk*. The Securities Act Defendants failed to adequately describe the risks as described in ¶ 138 above.
- 142. The failure of the Offering Documents to disclose the omitted material facts set forth above in ¶¶ 136 and 138 violated Item 303, because the undisclosed facts were known and would (and did) have an unfavorable impact on the Company's sales, revenues, and income from continuing operations. This also violated Item 503(c), because these specific risks were not

⁴ Amended and relocated as Item 105 of SEC Regulation S-K between the time of the Offering and the time of the filing of the complaint.

adequately disclosed, or disclosed at all, even though they were some of the most significant factors making an investment in electroCore speculative or risky.

C. Events and Disclosures Following the Offering

- 143. First, although claiming in the Offering Documents to have agreements in place with access to 17 million lives, as described above, the CVS agreement did not begin coverage until the first quarter of 2019. $See \P 181, 187$
- 144. Further, as more fully described in Sections VII.B and VII.C. below, beginning with electroCore's first quarter 2019 earnings release on May 14, 2019, electroCore began to disclose the specific difficulties it faced in obtaining commercial insurance coverage. Indeed, less than one year after its IPO, on May 29, 2019, the Company announced a comprehensive redeployment and cost reduction plan. And, on June 10, 2019, the Company announced that defendant Amato would be "stepping down" as CEO, although remaining with electroCore "for a transition period."
- 145. By the commencement of this action, electroCore stock was trading as low as \$1.25 per share, a nearly 92% decline from the \$15.00 per share IPO price.

D. Causes of Action Under Sections 11, 12(a)(2) and 15 of the Securities Act

COUNT I

For Violations of Section 11 of the Securities Act (Against electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the Underwriter Defendants)

146. Lead Plaintiff repeats and realleges each of the allegations contained above as if fully set forth herein. This Count is predicated upon electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the Underwriter Defendants' strict liability for making false and materially misleading statements and omissions in the Registration Statement.

- 147. This Count does not sound in fraud. Any proceeding allegations of fraud, fraudulent conduct, or improper motive are specifically excluded from this Count. Lead Plaintiff does not allege for this Count that the Securities Act Defendants named herein had scienter or fraudulent intent, which are not elements of this claim, except that any challenged statements of opinion or belief made in connection with the IPO are alleged to have been materially misstated statements of opinion or belief when made.
- 148. This Count is brought pursuant to Section 11 of the Securities Act on behalf of all persons who purchased electroCore common stock pursuant to and/or traceable to the Company's IPO, in which shares registered under the Registration Statement were sold.
- 149. As alleged, the Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary in order to make the statements not misleading, and omitted to state material facts required to be stated therein.
- 150. As issuer of the shares, electroCore is strictly liable to Lead Plaintiff and the Class for the misstatements and omissions in the Registration Statement.
- 151. Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are strictly liable for the contents of the Registration Statement based upon their status as officers and/or directors of the Company and/or because they signed or authorized the signing of the Registration Statement on their behalf pursuant to Section 11(a)(1)-(3) of the Securities Act. Each of these defendants was responsible for the contents and dissemination of the Offering Documents, which were inaccurate and misleading, contained untrue statements of material facts, and omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein. Each of these

defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement and ensure that they were true and accurate and not misleading. In the exercise of reasonable care, these defendants should have known of the material misstatements and omissions contained in the Registration Statement. Accordingly, each of these defendants is liable to Lead Plaintiff and the other members of the Class.

- 152. The Underwriter Defendants are strictly liable for the contents of the Registration Statement as named underwriters pursuant to Section 11(a)(5) of the Securities Act.
- 153. None of the Securities Act Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement and identified at ¶¶ 134-35 were true and without omissions of any material facts and were not misleading.
- 154. By reason of the conduct alleged herein, each the Securities Act Defendants named in this Count violated, and/or controlled a person who violated, Section 11 of the Securities Act.
- 155. Lead Plaintiff and other members of the Class acquired electroCore common stock pursuant and/or traceable to the Registration Statement for the IPO.
- 156. Lead Plaintiff and the Class have sustained damages. The value of electroCore's common stock has declined substantially below the Offering price and below the price Lead Plaintiff and the other members of the Class paid for their electroCore common stock subsequent to and due to the Securities Act Defendants' violations of law.
- 157. At the time of their purchases of electroCore common stock, Lead Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts. Less than one year has

elapsed from the time that Lead Plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time of the filing of the initial complaint in this action. Less than three years has elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Lead Plaintiff filed this Complaint.

158. By virtue of the foregoing, Lead Plaintiff and the other members of the Class are entitled to damages under Section 11 as measured by the provision of Section 11(e), from the Securities Act Defendants and each of them, jointly and severally.

COUNT II

For Violations of Section 12(a)(2) of the Securities Act (Against electroCore and the Underwriter Defendants)

- 159. Lead Plaintiff repeats and realleges each of the allegations contained above as if fully set forth herein.
- 160. This Count does not sound in fraud. Any proceeding allegations of fraud, fraudulent conduct, or improper motive are specifically excluded from this Count. Lead Plaintiff does not allege for this Count that electroCore or the Underwriter Defendants had scienter or fraudulent intent, which are not elements of this claim, except that any challenged statements of opinion or belief made in connection with the IPO are alleged to have been materially misstated statements of opinion or belief when made.
- 161. This Count is brought pursuant to Section 12(a)(2) of the Securities Act on behalf of all persons who purchased electroCore common stock pursuant to and/or traceable to the Company's IPO against electroCore and each of the Underwriter Defendants.
- 162. The Prospectus contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted material facts required to be stated therein. The actions of solicitation by the defendants named in this Count include participating in the preparation of the false and misleading Prospectus, roadshow, and marketing

of electroCore's common stock to investors, such as Lead Plaintiff and the other members of the Class.

- 163. The defendants named in this Count owed to the purchasers of electroCore common stock, including Lead Plaintiff and other members of the Class, the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. By virtue of each of these defendants' failure to exercise reasonable care, the Prospectus contained misrepresentations of material facts and omissions of material facts necessary to make statements therein not misleading.
- 164. Lead Plaintiff and the other Class members did not know, nor could they have known, of the untruths or omissions contained in the Prospectus.
- 165. The defendants named in this Count were obligated to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission of material fact required to be stated in order to make the statements contained therein not misleading. None of the defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Prospectus were accurate and complete in all material respects. Had they done so, these defendants could have known of the material misstatements and omissions alleged herein.
- 166. This Count is brought within one year after discovery of the untrue statements and omissions in the Prospectus and within three years after the Company's shares were sold to the Class in connection with the Offering.
- 167. By reason of the conduct alleged herein, the defendants named in this Count violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violation,

Lead Plaintiff and the other members of the Class who purchased electroCore common stock pursuant and/or traceable to the Prospectus sustained substantial damages in connection with their share purchases. Accordingly, Lead Plaintiff and the other members of the Class who hold shares issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares with interest thereon or damages as allowed by law or in equity. Class members who have sold their electroCore shares seek damages to the extent permitted by law.

COUNT III

For Violations of Section 15 of the Securities Act (Against Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the CV Defendants)

- 168. Lead Plaintiff repeats and realleges each of the allegations contained above as if fully set forth herein.
- 169. This Count does not sound in fraud. Any proceeding allegations of fraud, fraudulent conduct, or improper motive are specifically excluded from this Count. Lead Plaintiff does not allege for this Count that the defendants named herein had scienter or fraudulent intent, which are not elements of this claim, except that any challenged statements of opinion or belief made in connection with the IPO are alleged to have been materially misstated statements of opinion or belief when made.
- 170. This Count is brought pursuant to Section 15 of the Securities Act against defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the CV Defendants.
- 171. Each of the Individual Defendants named in this Count acted as a controlling person of electroCore within the meaning of Section 15 of the Securities Act by virtue of his or her position as a director and/or senior officer of electroCore. By reason of their senior management positions and/or directorships at the Company, as alleged above, these defendants, individually

and acting pursuant to a common plan, had the power to influence and exercised the same to cause electroCore to engage in the conduct complained of herein. Further, the defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Lead Plaintiff and the Class. By reason of such conduct, the defendants named in this Count are liable pursuant to Section 15 of the Securities Act.

- 172. Each of the Individual Defendants named in this Count was a culpable participant in the violations of Section 11 of the Securities Act alleged in Count I above, based on their having signed the IPO Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.
- 173. The CV Defendants each had the ability to influence the polices and management of the Company at all relevant times by means of their control over the Company through the entities' managing members, defendants J. Errico and T. Errico. The CV Defendants also had a financial interest in taking the Company public and were critical to effectuating the Offering.
- 174. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Documents and identified at ¶¶ 134-35 were true and without omissions of any material facts and were not misleading.
- 175. By virtue of the conduct alleged herein, defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the CV Defendants are liable for the aforesaid wrongful conduct and are liable to Lead Plaintiff and the Class for damages suffered as a result of the primary Securities Act violations of electroCore.

VII. VIOLATIONS OF SECTIONS 10(b) AND 20(a) OF THE EXCHANGE ACT

176. The allegations contained in ¶¶ 177-276 below are made with respect to Lead Plaintiff's claims under Sections 10(b) and 20(a) of the Exchange Act only. Lead Plaintiff

disclaims any reliance upon these allegations or incorporation of these allegations in the Securities Act claims.

177. These Exchange Act claims are brought against the following defendants: electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis, *i.e.*, the Exchange Act Defendants.

178. The Exchange Act Defendants (with the exception of Posner) are makers of the statements contained in the Offering Documents. electroCore is the issuer of the statements, and Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis signed their names to those statements (or authorized the signing of), indicating that each was a maker thereof. The materially false and misleading statements and omissions as described in Sections V. and VI. above and the reasons for those statements' falsity and materiality are expressly incorporated and re-alleged as if fully set forth herein.

A. Additional Materially False and Misleading Misrepresentations and Omissions Actionable Under the Exchange Act

179. On November 13, 2018, the Company issued a press release, attached as Exhibit 99.1 to a Form 8-K filed with the SEC and signed by defendant Vraniak, titled, "electroCore, Inc. Announces Third Quarter Financial Results" (the "November 2018 Press Release"). The November 2018 Press Release stated, in relevant part:

Third Quarter 2018 and Recent Highlights

- Generated 4,516 gammaCore® prescriptions in the third quarter of 2018, with over 11,000 prescriptions written as of October 31, 2018
- Nearly 1,500 unique prescribing physicians through the third quarter of 2018, an increase of 48% from the second quarter
- Launched reloadable and rechargeable gammaCore Sapphire across the U.S. market
- Submitted 510(k) application to the FDA for the prevention of cluster headache

- Commercial payer coverage for 35 million lives beginning in the first quarter of 2019⁵
- National Institute of Health and Care Excellence (NICE) publication advising gammaCore for the treatment of cluster headache in the U.K.

"We are pleased with our performance in the third quarter and are encouraged by the positive prescription trends we are generating while we progress forward several clinical and strategic initiatives," said Frank Amato, Chief Executive Officer. "With continuing discussions and negotiations for payer coverage for an additional 90 million lives, and our increasing base of prescribing physicians, we are well positioned for gammaCore to be an early option for patients suffering from migraine and episodic cluster headaches."

Third Quarter Financial Results

electroCore recognized \$150,972 in net sales for the three months ended September 30, 2018. The decrease in net sales of \$132,267 versus the third quarter of 2017 contrasts with the significant increase in prescriptions during the same period as a result of a vast majority of prescriptions being dispensed under our patient voucher and copay assistance programs, as the Company continues negotiations with commercial payers for formulary coverage of gammaCore. The Company expects this trend to be temporary, as increased numbers of patients are expected to obtain commercial prescription coverage for gammaCore starting in January 2019. The Company dispensed approximately \$1.7 million in product sales value to patients through the patient voucher program.

- 180. The Company also held an earnings conference call on November 13, 2018 which was attended defendants Amato, Vraniak, and J. Errico. Defendant Amato started off the call, "describe[ing] the performance of our launch to date" and "talk[ing] about three key areas; sales force deployment and doctor coverage; *insurance reimbursement and the progress we are making with the payers*; and our overall sales strategy and performance."
 - 181. Among other things, Amato described the Company's payer progress as follows:

So where are we with the commercial payers and PBMs? Currently we have multiple reimbursement agreements in place. The first of which is the CVS Caremark agreement, which will go into effect on January 1, 2019. Under this agreement, we have been advised that approximately 30 million of the 65 million U.S. individuals managed by CVS Caremark will have access to our therapy as a Tier 3 product beginning in January of 2019. Potential access to the remaining 35

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⁵ Unless otherwise noted emphasis is added.

million lives will be gained through continuing negotiations with the payers within the CVS network.

182. An analyst with Evercore ISI inquired as to paid prescription growth and the Company's ability to reach agreements for reimbursement with payers to which defendant Amato responded as follows:

Josh Schimmer

It sounds like demand for the product has grown nicely. But at least relative to where some of the numbers were set, the ability to convert patients from a prescription to a paid prescription -- a label prescription to a paid prescription is lagging a little bit. So first of all, how should we think about the fourth quarter of 2018? Is this really a year where we shouldn't be expecting much in the way of paid prescription growth? We're also six weeks to the end of 2019 [sic], so maybe you could talk a little bit about your confidence of locking in some key PBM contracts so that you are more prepared for a swift adoption in 2019. And then as we think about the dynamics that drove this quarter, if we were looking at the start of 1Q '19, when you feel like you'll be a little bit better positioned for reimbursement, what might this quarter have to look like if you had that type of access secure?

Frank Amato

I think if we tack through the various questions here, the conversion from the gammaCore-S model to the gammaCore Sapphire model in the middle of October really positioned us to start to provide therapy for patients on a one or two month basis depending upon whether they were still appealing their insurer for either being denied access or they were waiting to hear back from the insurance company as to whether they were going to reimburse the product. We think there'll be additional revenue and access with the payers through the PA or the prior auth process through the fourth quarter. We're starting to see that already. I don't have any numbers to report at this point in time, but we're starting to see conversion there, especially since it's been three weeks since we've converted the market over to the Sapphire product.

With respect to our confidence with the PBMs, two weeks ago, I was out meeting with the folks at OptumRx. We're awaiting their contract proposal. ... We've already negotiated with ESI⁶ back in the latter part of the summer, an agreement, a PBM agreement that would, I believe, be honored by ESI. We'll learn more here when we hear back from the organization regarding their compendia. *They get their codes or our unique identifier code from First Databank. First Databank has two databases.* They have the Prizm system, which is where they put all the medical devices and the MedKnowledge system where they put all of the pharmaceutical products. *Since our code is like an NDC number, and ESI is a PBM, they only*

⁶ "ESI" refers to Express Scripts.

contract for that MedKnowledge group. So they are working very closely with Asembia. I was notified as of this morning that they're in current discussions with Asembia and First Databank on how to pull that code over into their systems so they can start honoring the agreement that we negotiated. So we're pretty confident that, by the early part of 2019, that there'll be an agreement in place with both ESI and hopefully OptumRx. ... So we're starting to see an escalation of the number of prescriptions that are being written, 4,500 for the third quarter. We already had 2,000 in the first month of the fourth quarter. So as we see that demand grow and we get access in the market, we think that we'll be on the type of trajectory for revenue in 2019 that most of the analysts were expecting.

183. Defendant Vraniak discussed the financial results and voucher program, stating:

For the quarter ending September 30, 2018, we reported GAAP revenue of \$150,972, a decrease of \$132,267 from the third quarter of 2017. This decrease is primarily due to the contra-revenue remaining as a result of our voucher program that extended into mid-July. Under this voucher program through mid-July, we would reimburse the specialty pharmacy for patient cost of gammaCore therapy at the time of dispense. This would be the basis for recognizing contra-revenue against products sold previously to our distributor. In mid-July, we shifted to the use of a free voucher program free voucher units, thereby, eliminating the need to reimburse the pharmacy for patient cost and the need to book contra-revenue. The cost of these units dispensed under the voucher program after mid-July will then book to promotional expense. And in this way, it appears much more like a sample program.

184. On November 14, 2018, electroCore filed with the SEC its quarterly report on Form 10-Q for the quarter ended September 30, 2018 (the "3Q18 10-Q"), signed by defendants Amato and Vraniak, and reiterating the financial results as reported in the November 2018 Press Release. Amato and Vraniak also signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") attesting to the accuracy of the financial reporting and the disclosure of any material changes to the Company's internal control over financial reporting, and stating that the quarterly report did "not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading;" that "[a]ny fraud, whether or not material, that involves management or other employees who have a significant role in the [Company's] internal control over financial

reporting" was disclosed and that "the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

185. Furthermore, the 3Q18 10-Q stated under the section titled "Risk Factors" that:

There have been no material changes during the three months ended September 30, 2018 to the risk factors discussed in our prospectus dated June 21, 2018, filed with the SEC, pursuant to Rule 424(b) under the Securities Act.

- 186. The statements in ¶¶ 179-85 above were materially false and/or misleading and failed to disclose material adverse facts. Specifically, the November 2018 Press Release, statements made on the related earnings conference call, and 3Q18 10-Q failed to disclose that:
 - electroCore's agreement with CVS for 15 million lives, let alone 30 million lives, was still being negotiated and currently only covered 7 million lives *at most* (*see* ¶¶ 78-85);
 - there were material adverse limitations to the payer agreements, including that gammaCore would not be included on CVS's template formulary and that in order for the coverage to apply, the prescription had to be written by a neurologist and the patient had to have failed with at least three other prescribed medications (*see* ¶¶ 79-80, 86-87);
 - (iii) there were key material adverse factors preventing access to payer coverage and reimbursement and subsequently materially harming sales of gammaCore and electroCore's financial results, including:
 - (a) that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment, needing to create a new gammaCore product version in order to receive the code (*see* ¶¶ 110, 113-15);

- (b) that the coding issue was not unique to just ESI, and that in order to be covered as a pharmacy benefit, gammaCore needed a drug code, but because it was not a traditional drug could not receive one and the largest database used by commercial payers, First Databank, did not list non-drug NDCs along with its drug codes and needed to develop a third database for codes like gammaCore, something that was not even developed until 2019 and not available until 2020 (*see* ¶¶ 111-12, 203);
- (c) that the voucher program changes in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18);
- (d) that as a result of the above, the voucher program would not "temporary" but in effect until December of 2019;
- (e) that as a result of the above, the Company would struggle to obtain agreements with payers for coverage and reimbursement; and,
- that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage (see ¶¶ 95, 99, 102-107, 202); and

- (iv) as a result of the foregoing, all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable;
- (v) as a result of the foregoing, the positive statements about electroCore's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis; and
- (vii) the risk factors listed in the Prospectus spoke of vague future contingencies and risks, misrepresenting or omitted material present facts regarding existing coverage, and specific material known risks to obtaining future coverage as described in ¶ 138 above.
- 187. On March 27, 2019, electroCore issued a press release, attached as Exhibit 99.1 to a Form 8-K filed with the SEC and signed by defendant Vraniak, titled "electroCore Announces Fourth Quarter and Full Year 2018 Financial Results," announcing the Company's financial results for the quarter and year ended December 31, 2018 (the "March 2019 Press Release"). The March 2019 Press Release stated in relevant part:

"During the fourth quarter, we continued to execute on our commercial growth plan, led by our ongoing progress toward increasing covered lives through productive discussions with national and regional payers," said Frank Amato, Chief Executive Officer of electroCore. "Notably, our fourth quarter results do not reflect the addition of covered lives from CVS Caremark, Highmark and the recently announced Federal Supply Schedule contract, all of which commenced reimbursement of gammaCore® beginning in the first quarter 2019.

188. The Company also held an earnings conference call on March 27, 2019 attended by defendants Amato, Vraniak and J. Errico. During the call, defendant Amato touted the Company's purported successes with gaining access to commercial lives, stating, in relevant part:

During the fourth quarter of 2018, there were more than 5800 prescriptions written, an increase of 30% over the third quarter. Momentum continued building into the fourth quarter with a favorable ramp. *However, these results have yet to reflect the*

positive effect reimbursement will have for gammaCore, which largely started in this year. Reimbursement that includes individuals managed by CVS Caremark, Highmark, as well as the Federal Supply Schedule and more specifically the Veterans Administration and Department of Defense.

* * *

Key to on our ongoing growth is continued expansion of insurance coverage or reimbursement among commercial payers. We remain on track to achieve 75 million covered lives by the middle of this year and 100 million by the end of the year. We had an impressive quarter-over-quarter growth in covered lives over the past two quarters. From 33 million in Q3 with an additional 21 million in Q4 and 5 million more we just announced recently, adding up to the approximate 60 million covered lives that we currently have in the United States.

* * *

Importantly, we remain on track to achieve 75 million covered lives by mid '19 and 100 million by year end. This is impressive growth from the approximate 60 million covered lives that we have currently and bodes well for future prescription and revenue growth.

* * *

Our reported fourth quarter 2018 GAAP revenue was \$368,000. We also dispensed approximately \$1.7 million worth of gammaCore prescriptions pursuant to ongoing promotional programs. These programs are designed for patients who do not yet have reimbursement, otherwise known as demand revenue. As such the potential demand product sales value of gammaCore prescriptions dispensed during the fourth quarter of 2018 was approximately \$2.1 million.

* * *

Key to on our ongoing growth is continued expansion of insurance coverage or reimbursement among commercial payers. We remain on track to achieve 75 million covered lives by the middle of this year and 100 million by the end of the year. We had an impressive quarter-over-quarter growth in covered lives over the past two quarters. From 33 million in Q3 with an additional 21 million in Q4 and 5 million more we just announced recently, adding up to the approximate 60 million covered lives that we currently have in the United States.

189. Defendant Amato also commented on the code issue with ESI, stating, in relevant

part:

As discussed previously, we have had some logistical challenges with one of the compendium organizations making the availability of our product codes to

pharmacy benefit managers a challenge. These issues have especially affected our negotiations with Express Scripts.

As a positive step in overcoming that challenge, I am pleased to report that in late February, the unique identifier code for gammaCore was lifted by unanimous recommendation of the National Council for Prescription Drug Programs, NCPDP. GammaCore now has a recognized dosing standard across all compendia, including First Databank. With this peace now in place, we look forward to additional positive announcements regarding expanding reimbursement in the coming months.

* * *

Obviously, there have been a number of PBMs that we've been in conversations with, namely Express Scripts, OptumRx, Involve Rx and others to name a few. We've been in discussions with ESI in the past few weeks here, ensuring that when they reach over to their compendium First Databank, that they can get back the gammaCore code, once the gammaCore code comes back, they can then get into a contract discussion with us, starts out with the term sheet and then moves toward a contract that they bring up to their back committee. So we think that, you know, over weeks, to the coming couple months here into the second quarter that it's likely that we'll be able to pull through one or more of those PBM opportunities.

With some of the other PBMs, they don't necessarily have to work with First Databank, I'm not sure who their compendia are, both for OptumRx and Envolve, it's just a matter of now working with their particular compendia to ensure that our code and that compendia have access to it. The NCPDP unanimous recommendation to have our code available across the United States should make it available to each and every compendia out there.

190. Vraniak commented on the purported demand driving voucher program, stating:

As Frank noted earlier, the majority of gammaCore prescriptions during the quarter were dispensed under promotional programs. As a result, we're proud to report that we've delivered an additional \$1.7 million of product sales value of gammaCore therapy to patients through our promotional programs.

This includes vouchers or free therapy and co-pay assistance. Through our co-pay assistance program, we assist patients who have obtained commercial coverage with up to \$100 of their co-pay at the time that gammaCore dispensed. We continue to believe these programs are accomplishing our objectives of providing patient therapy at no charge, demonstrating the benefits of gammaCore therapy to physicians who write prescriptions and promoting U.S. commercial payer coverage and coverage discussions as a result of patient and physician demand.

191. An analyst from Evercore ISI questioned the Company's cash burn and defendant

Amato reassured investors that it was not an issue, stating:

Yes, I think you've hit the nail on the head. When Glenn references a \$4 million a month cash burn, that's an average burn for the year we expect. We've had that burn up until this point for the most part, that is outflows what Glenn is reporting on. So that's what our expenses are going to be. With respect to revenue that comes in to offset some of that burn, we do expect that to be sequential and accelerated through the year, as I mentioned on the call earlier.

So, when we have some of this reimbursement that will come through for CVS Caremark, Highmark, also the federal supply schedule and any new PBMs and/or commercial insurance plans that we're expecting this year, additional Blue Cross Blue Shield plans to be exact, that will offset to a great degree some of that burden.

I just want to add one other comment in here, and that is, although the burn will be on average monthly \$4 million, we'll have months where we'll pay bonuses to the sales force and to folks in headquarters, and that'll pop up here and there on a monthly basis. But on average, we expect a \$4 million outflow on expense or cash burn for the Company.

- 192. The statements in ¶¶ 187-91 above were materially false and/or misleading and failed to disclose material adverse facts. Specifically, the March 2019 Press Release and statements made on the related earnings conference call were materially false and misleading and/or failed to disclose that:
 - (i) electroCore's agreement with CVS only covered *at most* 7 million lives during 2018 (see ¶¶ 78-81);
 - there were material adverse limitations to the payer agreements, including that gammaCore would not be included on CVS's template formulary and that in order for the coverage to apply, the prescription had to be written by a neurologist and the patient had to have failed with at least three other prescribed medications (*see* ¶¶ 79-80, 86-87);
 - (iii) there were key material adverse factors preventing access to payer coverage and reimbursement and subsequently materially harming sales of gammaCore and electroCore's financial results, including:

- that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment, needing to create a new gammaCore product version in order to receive the code (see ¶¶ 110, 113-15);
- that the pharmacy benefit drug code issue was not unique to ESI and while some "PBMs don't have to necessarily work with First DataBank," First Databank is the largest database used by commercial payers, and First Databank did not list non-drug NDCs along with its drug codes and needed to develop a third database for codes like gammaCore, something that was not even developed until 2019 and not available until 2020 (see ¶¶ 111-12, 203);
- (c) that the voucher program changes in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18);
- (d) that as a result of the above, the Company would struggle to obtain agreements with payers for coverage and reimbursement; and,
- (e) that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the

paperwork and following up on coverage (see $\P\P$ 95, 99, 102-107, 202); and

- (iv) as a result of the foregoing, all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable; and,
- (v) as a result of the foregoing, the positive statements about electroCore's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.
- 193. On March 28, 2019, the Company filed its 2018 Form 10-K with the SEC, signed by defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra and Tullis, and affirming the information provided in the March 2019 Press Release. Defendants Amato and Vraniak also signed certifications, containing the same statements as in ¶ 184 pursuant to SOX.
- 194. The 2018 Form 10-K repeatedly discussed the Company's purported current payer agreements and access to commercial lives and ongoing negotiations. Specifically, the 2018 Form 10-K stated:

As of January 2019, we have agreements or arrangements with commercial payers, one pharmacy benefit manager, or PBM and the Federal Supply Schedule, or FSS, that we estimate provide for reimbursement for gammaCore as either a pharmacy benefit or medical benefit for approximately 53 million lives in the United States. Although there can be no assurance of success, our payer access team is negotiating contracts with several additional insurance plans and PBMs covering an additional approximately 90 million commercial lives, and in clinical review with plans covering an additional approximately 50 million lives.

* * *

Commercializing our therapy through traditional pharmaceutical channels. Our monthly prescription model, made possible by our noninvasive delivery modality, empowers medical professionals to prescribe nVNS on a monthly basis through the same channel they would prescribe any other specialty medication. Our RFID refill card enables us to offer nVNS therapy on a monthly basis, at the price of a branded pharmaceutical, which is typical of a traditional drug reimbursement model

managed by pharmacy benefit managers and other commercial payers. Beginning in the first quarter of 2019, we have agreements with commercial payers and the Federal Supply Schedule (Veterans Administration and Department of Defense) that we estimate provide reimbursement of gammaCore for approximately 53 million lives. Although there can be no assurance of success, we continue discussions with additional payers and PBMs regarding up to an additional 90 million lives in the United States with a goal of securing reimbursement for an aggregate of 75 million lives in the United States by the beginning of the third quarter of 2019, and an aggregate of 100 million lives in the United States by the end of 2019.

* * *

Drive reimbursement of our therapy. We have been and are actively engaging with over 50 national and regional commercial insurance payers, as well as the Federal Supply Schedule in the United States, with the goal of securing reimbursement coverage. These efforts in 2018 culminated with the initiation of estimated coverage for approximately 53 million lives in the United States as of January 2019. With continuing payer discussions regarding up to an additional 90 million lives, we are seeking to expand the number of covered lives in the United States to an aggregate of 75 million by the beginning of the third quarter of 2019, and to an aggregate of 100 million by the end of 2019, although there can be no assurance of success.

* * *

As of January 2019, we have agreements or arrangements with commercial payers, one PBM and the FSS that we estimate provide for reimbursement for gammaCore as either a pharmacy benefit or medical benefit for approximately 53 million lives in the United States. Although there can be no assurance of success, our payer access team is negotiating contracts with several additional insurance plans and PBMs covering approximately 90 million commercial lives in the United States, and in clinical review with plans covering an additional approximately 50 million lives in the United States. With continuing payer discussions regarding up to an additional 90 million lives, we are seeking to expand the number of covered lives in the United States to 100 million in 2019.

195. The 2018 Form 10-K also discussed the voucher program instituted during 2018, stating, in relevant part:

In February 2018, we instituted a voucher program under which new patients could acquire one-month of gammaCore therapy at no cost from our specialty pharmacy if their insurance provider failed to reimburse for our therapy. Under this program, therapy being dispensed to patients by our specialty pharmacy were commercial goods that had been sold by us to our distributor and in turn re-sold to the specialty pharmacy. We reimbursed the specialty pharmacy an amount equal to the amount

the specialty pharmacy would have received had a commercial payer reimbursed for this unit, inclusive of any copay requirement and the contracted dispensing fee.

- 196. The above 2018 Form 10-K statements in ¶¶ 193-195, were materially false and/or misleading and omitted to disclose material information necessary to make its statements not misleading. Specifically, the 2018 Form 10-K:
 - (i) omitted the material fact that electroCore's agreement with CVS only covered 7 million lives *at most* during 2018 (*see* ¶¶ 78-81);
 - (ii) materially mislead investors to believe that Company had agreements in place with multiple insurance companies (*see* ¶¶ 74-107);
 - (iii) omitted key material adverse limitations for the purported "commercial payor" agreements, including that gammaCore would not be included on CVS's template formulary and that in order for the coverage to apply, the prescription had to be written by a neurologist and the patient had to have failed with at least three other prescribed medications (*see* ¶ 79-80, 86-87);
 - (iv) omitted key material adverse factors preventing access to payer coverage and reimbursement and subsequently materially harming sales of gammaCore and electroCore's financial results, including:
 - that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment, needing to create a new gammaCore product version in order to receive the code (see ¶¶ 110, 113-15);
 - (b) that the pharmacy benefit drug code issue was not unique to ESI and while some "PBMs don't have to necessarily work with First DataBank," First Databank is the largest database used by

- commercial payers, and First Databank did not list non-drug NDCs along with its drug codes and needed to develop a third database for codes like gammaCore, something that was not even developed until 2019 and not available until 2020 (see ¶¶ 111-12, 203);
- that the voucher program change in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18);
- (d) that as a result of the above, the Company would struggle to obtain agreements with payers for coverage and reimbursement; and,
- that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage (see ¶¶ 95, 99, 102-107, 202); and
- (v) as a result of the foregoing, all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable; and,
- (vi) as a result of the foregoing, the positive statements about electroCore's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.

- 197. The 2018 Form 10-K risk disclosures do not contradict the misrepresentations or omissions set forth above. Instead, they speak of vague future contingencies and risks regarding the possibility that that third party payers may not agree to cover gammaCore. The disclosures, however, continued to misrepresent or omit material present facts regarding existing coverage, and specific known risks of obtaining future coverage.
 - 198. Specifically, the 2018 Form 10-K risk disclosures:
 - (i) materially mislead investors to believe that Company had agreements in place with multiple insurance companies (see ¶¶ 74-107);
 - (ii) omitted that there were then-existing substantial issues preventing payer coverage not only for gammaCore as a pharmacy benefit, but also as medical device and thus commercialization of gammaCore was *already* being negatively affected, including:
 - that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment, needing to create a new gammaCore product version in order to receive the code (see ¶¶ 110, 113-15);
 - that the pharmacy benefit drug code issue was not unique to just one PBM and while some "PBMs don't have to necessarily work with First DataBank," First Databank is the largest database used by commercial payers, and First Databank did not list non-drug NDCs along with its drug codes and needed to develop a third database for codes like gammaCore, something that was not even developed until 2019 and not available until 2020 (see ¶¶ 111-12, 203);

- (c) that the voucher program change in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18);
- (d) that as a result of the above, the Company would struggle to obtain agreements with payers for coverage and reimbursement; and,
- that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage (see ¶¶ 95, 99, 102-107, 202).
- 199. As a result of the foregoing, the disclosed risks were not a mere possibility, a "may" or "could" occur, but were in fact occurring and would lead to modification of the Company's commercialization strategy and have a material adverse effect on the sales of gammaCore and the results of operations.

B. The Truth Is Slowly Revealed

200. On May 14, 2019, electroCore issued a press release, also filed with the SEC as Exhibit 99.1 to a Form 8-K signed by defendant Posner, titled "electroCore Announces First Quarter 2019 Financial Results" (the "May 2019 Press Release"). The May 2019 Press Release stated, in relevant part:

First Quarter 2019 and Recent Highlights

- Nearly 2,200 prescribing physicians through the first quarter of 2019, up from approximately 1,800 in the fourth quarter of 2018
- Total prescriptions written were approximately 6,100 in the first quarter of 2019 compared to 5,800 in the fourth quarter of 2018
- Prescriptions dispensed were approximately 3,000 in in the first quarter of 2019, relatively unchanged from the fourth quarter of 2018

* * *

"Our first quarter 2019 operating results are only beginning to reflect the positive steps that we took during the second half of last year," said Frank Amato, chief executive officer of electroCore. "Notably, our first quarter results do not fully reflect the positive impact of new payers that were implemented during the quarter, including CVS Caremark, Highmark, and the Veteran's Administration or Partners for Coverage, our expanded free goods program. We are establishing a new approach to headache therapy and recognize that our growth will be gated by the realities of carving a new market position in a lucrative but crowded therapeutic segment. gammaCore Sapphire has a unique position as the only non-invasive vagus nerve stimulation device approved by FDA to treat both migraine and cluster headache, and the only therapy of any type approved for the prevention of cluster headache. We are working with payers to help them decide how to pay for a product that can be reimbursed through multiple pathways. We are pleased by our accomplishments to date and believe our market penetration will increase as the awareness of our therapy expands and when we add further payer coverage."

First Quarter 2019 Financial Results

* * *

Cash and cash equivalents and marketable securities at March 31, 2019 totaled \$52.4 million, as compared to \$68.6 million at December 31, 2018. *The net cash burn of \$16.2 million for the quarter ended March 31, 2019*, included working capital uses of cash due to a \$1.6 million increase in inventory and approximately \$2.1 million of payments related to 2018 accrued compensation.

201. The disappointing earnings results and purported delay of positive results from new payers did not reveal the full truth, and on the earnings conference call the same day, certain defendants continued to make materially false and misleading statements and omit material facts while further correcting previous statements.

202. On the call, defendant Amato again touted the "momentum" of gaining "patients, physicians, and payers," while revealing the abysmal reimbursement numbers and extra onerous requirements under certain agreements, stating, in relevant part:

Each of the targeted 33 individual military treatment facilities and 80 Veterans Administration centers require an understanding of how its local distribution process works. To that end, our commercial team brought 20 military facilities on line that purchased product during the first quarter. Similarly, regarding patients covered by the three large PBM networks, CVS Caremark, Express Scripts and OptumRx, more than 5,000 prescriptions have been filed -- filled under the Partners for Coverage program, the prior voucher program or through patient self-pay.

The majority of these prescriptions await approval of the required prior authorization and represent potential reimbursement. We are starting to see the log jam break with a better than 250% increased from Q4 to Q1 in reimbursed prescriptions seen through the CVS Caremark agreement. We are still in the early days of the implementation of the CVS Caremark agreement. So, the increases are over a small but now growing base and we are encouraged by the trend. Importantly, the April numbers show a continuation of this growth.

With this in mind in the first quarter 2019, we were able to realize GAAP revenue of approximately \$410,000, about 11% growth over the fourth quarter. We also dispensed in the U.S. an additional 1.6 million worth of gammaCore prescriptions through the ongoing promotional programs, which include both our Partners for Coverage program and co-pay assistance.

In total, the potential demand product sales value of gammaCore prescriptions dispensed during the first quarter of 2019 was similar to what we reported to the fourth quarter of 2018 were approximately \$2 million. As more of these promotional descriptions get reimbursed, we expect to see it reflected in GAAP revenue and will continue the revenue ramp that we are anticipating this year.

* * *

In the PBM channel, our agreement with CVS Caremark went into effect in January of this year. gammaCore is currently a non preferred branded product requiring a co-pay currently covered to our co-pay assistance that the prescription be written by a neurologist and the patient has failed at least three other prescribed medications.

To date, over 1,600 CVS Caremark patients have been prescribed gammaCore. Nearly 1100 prior authorization requests have been sent to prescribing physicians for which 800 responses have been received in return. Because the paper work is not only still correctly we are working closely with neurologist to whole new ability to provide required information to CVS Caremark accurately.

- 203. On the call, defendant Amato also admitted that a standard that "universalizes our codes for inclusion in all pharmacopoeia" was not developed until 2019 and that First Databank, the largest database used by commercial payers, did not agree to "build[] a third database which [would] include all the codes for [gammaCore]" until 2019.
- 204. Defendant Posner stated that the promotional programs "are accomplishing our objectives of providing patient therapy at no charge, demonstrating the benefits of gammaCore therapies to physicians writing prescriptions, and promoting U.S. commercial payer covers and covers discussions as a result of patient and physician demand."
- 205. In answering a question from an analyst with Evercore ISI, defendant Amato admitted that electroCore had a lack of agreements with insurance companies, stating: "We think that the medical plans or the insurance plans *will start to come on* with medical benefit reimbursement and those will be largely Blue Cross Blue Shield plans"
- 206. On this news, electroCore's share price fell \$1.58 per share, or 29.64%, from a closing price per share of \$5.33 on May 14, 2019 to a closing price per share of \$3.75 on May 15, 2019.
- 207. On May 15, 2019, electroCore filed with the SEC its quarterly report on Form 10-Q for the quarter ended March 31, 2019 (the "1Q19 10-Q"), affirming the financial results as reported in the May 2019 Press Release. The 1Q19 10-Q was signed by defendants Amato and Posner and contained their signed certifications, containing the same statements as in ¶ 184 pursuant to SOX.
- 208. The 1Q19 10-Q once again highlighted the voucher program as a mechanism that purportedly permitted the Company to gain access to commercial payers:

In February 2018, we began a formal physician training program engaging key opinion leaders throughout the United States to highlight the clinical evidence and

benefits of gammaCore for the acute treatment of pain associated with both migraine and episodic cluster headache and to train their colleagues on how to prescribe gammaCore. Concurrently, we began a program that provided these trained physicians with vouchers, which allowed them to provide new patients with a one-time 31-day prescription at no charge to the patient. This voucher program was implemented with three goals: to provide patients therapy at no charge; to demonstrate to physicians the benefits of gammaCore therapy; and to prompt U.S. commercial payers to provide pharmacy benefit coverage for the product as a result of their observation of patient demand for the therapy. This program has resulted in significant increases in prescriptions for gammaCore and has prompted negotiations with numerous commercial payers, resulting in non-preferred medical and pharmacy reimbursement in approximately 10 million lives and medical exception coverage for an additional 30 million pharmacy benefit lives in the first quarter of 2019.

209. Furthermore, the 1Q19 10-Q stated under the section titled "Risk Factors" that:

There have been no material changes during the three months ended March 31, 2019 to the risk factors discussed in our Annual Report on Form 10-K filed with the SEC.

- 210. The statements in ¶¶ 200-205 and 207-209 above were materially false and/or misleading and failed to disclose material adverse facts. Specifically, the May 2019 Press Release, statements made on the related earnings conference call, and 1Q19 10-Q failed to disclose:
 - (i) that there were key material adverse factors preventing access to payer coverage and reimbursement and subsequently materially harming sales of gammaCore and electroCore's financial results, including:
 - that gammaCore was not eligible for an HCPCS code and may not be eligible for an E-Code for Durable Medical Equipment, needing to create a new gammaCore product version in order to receive the code (*see* ¶¶ 110, 113-15);
 - (b) that the voucher program changes in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated

- demand for gammaCore, making it less likely for them to agree to coverage (see ¶¶ 116-18);
- (c) that as a result of the above, the Company would struggle to obtain agreements with payers for coverage and reimbursement; and,
- d) that as a result of the above, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps, increasing burdens on physicians and also increasing expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage (see ¶¶ 95, 99, 102-107, 202); and
- (ii) as a result of the foregoing, all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable;
- (iii) as a result of the foregoing, the positive statements about electroCore's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis; and
- (iv) the risk factors listed in the 2018 Form 10-K spoke of vague future contingencies and risks, misrepresenting or omitted material present facts regarding existing coverage, and specific material known risks to obtaining future coverage as described in ¶ 198 above.
- 211. Just over two weeks after announcing the disappointing first quarter 2019 results, on May 29, 2019, the Company issued a press release, also filed with the SEC as Exhibit 99.1 to

a Form 8-K signed by defendant Posner, titled "electroCore Announces Comprehensive Redeployment and Cost Reduction Plan." The press release stated, in relevant part:

electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced that *management and the Board of Directors are making significant adjustments to the deployment of personnel and resources across the organization*. The effort is intended to focus the Company on currently available and near-term revenue opportunities and on clinical programs specifically designed to expand the gammaCoreTM product labeling. *To achieve this goal the Company is right-sizing across its organization, including its field sales force and clinical operations*. The Company will focus its resources on high-value geographic and other sales territories where the current prescriber base and regional payer coverage are most concentrated including:

- i. Regional payers, some of whom have recently amended their policies to permit reimbursement for electroCore's principal offering, gammaCoreTM.
- ii. The Veterans Administration and Department of Defense, covered under the Federal Supply Schedule contract secured by the Company in December 2018.
- iii. The United Kingdom, where a recent Innovative Technology Program cluster headache treatment award offers the Company the potential to generate revenue.
- iv. Other potential revenue opportunities in the pain management field.

The Company will continue to pursue relationships with pharmacy benefit managers.

electroCore also announced that it is scaling back its clinical development program as part of the redeployment of resources. Changes include the postponement of several planned studies while focusing on opportunities to broaden the approved indications for gammaCoreTM products. The Company is also reducing its medical affairs activities consistent with its revised commercial plan.

The broad-based redeployment and expense reduction plan will be fully implemented by the end of the second quarter of 2019. Beginning in the third quarter of 2019, the Company's average quarterly cash burn is expected to be less than \$7.0 million through 2020, compared to its previously reported expected burn of \$12.0 million per quarter. *Inclusive of one-time charges of approximately \$350,000 associated with implementation of this plan, the Company's second quarter cash burn is expected to be between \$11.0 million and \$11.5 million.* This expense reduction plan is further bolstered by the decision of the Company's independent directors to forgo all cash compensation for their Board service effective June 1, 2019, as well as the willingness of Frank Amato, the Company's chief executive officer, to voluntarily accept a 10% reduction in base annual cash compensation for the next 12 months, which is expected to be offset by a grant of

restricted stock units valued at \$50,000 on June 7, 2019, the date of the Company's annual meeting of stockholders.

On March 31, 2019, the Company had \$52.4 million of cash, cash equivalents and marketable securities. Based on its current cash resources and cash flow projections, and after giving effect to the anticipated cost savings from the comprehensive redeployment and cost reduction plan, electroCore believes that it will have adequate resources to fund its operations into the beginning of 2021.

Mr. Frank Amato said, "Although we are cognizant of the pain and disappointment that may be experienced by those employees who will be separating from the Company as we reduce our workforce from 91 to 55 positions under this program, the Board and management believe the adjustments to the expenditure of our resources are necessary as we respond to evolving market forces in the headache field. As was shared on our most recent earnings call, there are several promising commercial channels capable of providing significant sales acceleration.

- 212. On this news, electroCore's share price fell \$0.11, or over 5%, to close at \$1.95 per share on May 30, 2019, and continued to drop over the next two trading days, closing at \$1.65 per share on June 3, 2019.
- 213. On August 13, 2019, the Company issued a press release, attached as Exhibit 99.1 to a Form 8-K filed with the SEC and signed by defendant Posner, titled "electroCore Announces Second Quarter 2019 Financial Results" (the "August 2019 Press Release"). The August 2019 Press Release stated, in relevant part:

Second Quarter 2019 and Recent Highlights

* * *

• 510(k) premarket notification submission for migraine prevention accepted by FDA

* * *

"The comprehensive redeployment and cost reduction plan that we announced in May has made electroCore a more efficient organization capable of quickly reacting to changes in the rapidly evolving headache market. We believe our sharpened focus on our existing or near-term revenue generating opportunities is prudent while we continue to work to add the support of larger payers, which can take some time to bring across the finish line. We believe our non-invasive vagus nerve stimulation technology has applicability across a broad range of high-value

indications, and we expect that we will be able to sustain or accelerate our current growth trajectory," Mr. Amato concluded.

Migraine Prevention Label Expansion Update

In July 2019, the FDA accepted for review electroCore's 510(k) premarket notification for a new indication for use of gammaCore for the prevention of migraine. Accordingly, the company continues to enroll subjects in the Premium 2 clinical trial to support the label expansion into migraine prevention, and to support the commercialization of gammaCore as a migraine prevention therapy should the indication receive FDA clearance. The company expects to receive the FDA's decision by the end of 2019 and to complete enrollment in Premium 2 in the first half of 2020.

Second Quarter 2019 Financial Results

For the quarter ended June 30, 2019, electroCore reported net sales of approximately \$623,000, as compared to approximately \$410,000 in the first quarter of 2019. The increase in revenue reflects increased sales in the United States and the United Kingdom.

Total operating expenses for second quarter of 2019 were approximately \$12.7 million, as compared to approximately \$16.4 million for the second quarter of 2018. The decrease was due primarily to a reduction in SG&A expense, which declined to approximately \$9.4 million in the second quarter 2019 from approximately \$12.0 million for the comparable period in 2018, primarily driven by a reduction in both marketing related costs and stock compensation expense. The current quarter included restructuring charges of approximately \$850,000 in connection with the comprehensive deployment and cost reduction plan announced in May.

Operating loss for the second quarter of 2019 was \$12.4 million as compared to an operating loss of \$16.2 million in the second quarter of 2018.

Cash and cash equivalents and marketable securities at June 30, 2019 totaled approximately \$41.1 million, as compared to approximately \$68.6 million at December 31, 2018. Net cash burn for the quarter ended June 30, 2019 was approximately \$11.2 million, consistent with the previously stated expectation included in the Company's May press release announcing the comprehensive redeployment and cost reduction plan. Net cash burn for the quarter ended March 31, 2019 was approximately \$16.2 million.

As previously disclosed, beginning with the third quarter of 2019, the Company anticipates that its average quarterly cash burn will be less than \$7 million at least through 2020. *electroCore anticipates that its cash burn for some quarters may exceed \$7 million due to working capital adjustments and one-time payments*. Based on its current cash resources, and revenue and expense forecasts, electroCore believes that it will have adequate resources to fund its operations into the beginning of 2021.

- 214. An earnings conference call was also held on August 13, 2019. During this call, defendant Amato reiterated the key points from the August 2019 Press Release and again mentioned the recent 510(k) submission to the FDA for migraine prevention, stating "[l]ast month [the] FDA accepted our 510(k) submission to expand gammaCore's label into migraine prevention, and we expect to see the agent's decision by the end of the year."
- 215. On this disappointing financial news, electroCore's share price fell \$0.17 per share, or over 10%, from a closing price per share of \$1.56 on August 13, 2019 to a closing price per share of \$1.39 on August 14, 2019.
- 216. Although according to CW5, electroCore knew by August 2019 (if not earlier) that the FDA had concerns about the robustness of electroCore's data supporting the use of gammaCore for migraine prevention, the Exchange Act Defendants did not reveal such knowledge until forced to do so. On September 25, 2019, the Company revealed that the FDA had requested more information and analysis of clinical data for electroCore's 510(k) submission, which the Company had submitted in order to expand the use of gammaCore. The press release stated, in relevant part:

electroCore, Inc. (Nasdaq: ECOR, or the "Company"), a commercial-stage bioelectronic medicine company, today announced that the U.S. Food and Drug Administration ("FDA") has requested more information and analysis of the clinical data included in the Company's premarket notification, or "510(k)" submission, seeking an expanded indication for the use of gammaCoreTM (non-invasive vagus nerve stimulator). Although the Company has 180 days to respond to FDA's request, the Company expects to meet with the FDA in the fourth quarter to discuss the information request. gammaCoreTM is currently FDA-cleared for the treatment of pain associated with episodic cluster headache and migraine headache, and adjunctive use for the prevention of cluster headache.

The data submitted in the 510(k) include the results of the Premium 1 study, a randomized, double-blind, sham-controlled trial of gammaCoreTM....

"We look forward to meeting soon with the FDA to discuss our 510(k) submission and are committed to working with the agency to address their questions as quickly as possible," said Tony Fiorino, Chief Medical Officer of electroCore. "Meanwhile we continue to recruit subjects into the Premium 2 study which we anticipate will further define the clinical utility of gammaCoreTM in the migraine space."

217. On this news, the Company's share price fell \$0.79, over 23%, to close at \$2.57 per share on September 25, 2019, on unusually heavy trading volume.

C. <u>Post-Class Period Events</u>

- 218. The material magnitude of the known, but undisclosed, issues with obtaining commercial payer coverage and the effects of the voucher program only became more apparent after the end of the Class Period.
 - 219. For example, the voucher program was cancelled in December 2019.
- 220. Then beginning in January 2020, the Company stated that the CVS contract only pays for gammaCore prescriptions for beneficiaries with a certain benefit design with only 5 million CVS members having that benefit design.
- 221. On January 13, 2020, the Company issued a press release titled "electroCore Provides Business Update and Select Financial Guidance." The press release stated that the main focus for profit generation would be with the Federal Supply Schedule (and related VA and DOD treatment facilities) and with the UK's National Health Services, not PBMs, insurance companies or other commercial payers.
- 222. Last, as discussed above at ¶115, the Company and certain defendants have effectively admitted to the material importance of the HCPCS code, mentioning obtaining the code no less than eleven times between August 13, 2020 and July 13, 2021, and dedicating a press release to the receipt of a code and labelling it "a major U.S. reimbursement milestone." In fact, on the Company's fourth quarter 2020 earnings call, CEO Daniel Goldberger stated:

The new, the hicks picks [sic] code that goes live in April is a huge step forward. Right now, all of our prescriptions get coded to miscellaneous, once we have a unique code that sets the stage for us to negotiate with the regional max about Medicare coverage. But even more importantly, it streamlines the process for the national and regional private insurers to do the same, to establish unique coverage, to add us to more and more of the benefit plan.

So, all that work is going to be kicking off really in earnest in April once the code goes live, and we can run test scripts, and we can have specific conversations with different insurance companies around their benefit plans. So, a lot of work yet to do over the course of 2021. Look for additional announcements about coverage decisions as we go through this year. But the revenue list is really going to come in 2022 as we can take advantage of those coverage [ph] Willington back half of the year.

D. <u>Additional Scienter Allegations</u>

- 223. As alleged herein, each of the Exchange Act Defendants acted with scienter in that they knowingly or recklessly disregarded that the information disseminated to the public contained materially false and/or misleading information and omitted material information. Throughout the Class Period, the Exchange Act Defendants acted intentionally or in such a deliberately reckless manner as to constitute a fraud upon Lead Plaintiff and the Class. Such actions caused the price of electroCore securities to be artificially inflated.
- 224. In their respective roles as officers and/or directors of electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis were able to, and did, control the information disseminated to the investing public in the Company's various SEC filings, press releases, and other public statements during the Class Period. As a result, each had the opportunity to falsify the information provided to the public regarding electroCore's business and performance.

1. electroCore's \$77.7 Million IPO In the Face of Mounting Competition

225. With numerous competitors receiving increasing FDA approvals and coming to market with devices and drugs treating the same patients as gammaCore (¶¶ 62-70), the Exchange Act Defendants had to move swiftly to obtain market share. In order to do so, the Company needed to raise money in order to commercialize gammaCore. The Exchange Act Defendants' fraudulent scheme and materially false and misleading statements and omissions ensured the success of the Company's entry into the public equity markets.

226. The Exchange Act Defendants' materially false and misleading statements and omissions in the Offering Documents allowed electroCore to sell 5.98 million shares of common stock at \$15.00 per share during its IPO, garnering net proceeds of more than \$77 million, cash electroCore needed to continue to operate with only \$1.5 million in cash and cash equivalents as of March 31, 2018, and commercialize gammaCore.

2. Admitted Knowledge and Core Operations

- 227. electroCore was (and still is) an extremely small company with only 64 employees at the time of the IPO, increasing to 91 employees in early 2019 and then reducing the number of employees to 51 in May 2019. J. Errico and T. Errico founded the Company in 2005; Amato and Vraniak had been with the Company since 2012 and 2016, respectively; and Colucci, Moody, and Tullis had served as directors for at least a year prior to the IPO, if not more.
- 228. CW7 commented that because electroCore was a relatively small company, it was fairly easy to keep senior leaders up-to-date on various aspects of the company, adding that regular meetings were "a way to talk to everybody" and "let other departments know what's going on in their department. They tried to let us know as much as possible."
- 229. electroCore's Offering Documents and 2018 Form 10-K both touted the Company's "[h]ighly experienced management team" and listed it as a "Competitive Strengths":

Our management team includes a diverse group of executives with significant experience in senior positions in the pharmaceutical and medical device industries, including positions at Pfizer Inc, Merck & Co., Novartis International AG, Stryker Corporation and Zimmer Biomet. Members of our team have been involved in the launch and marketing of products including Motrin, Celebrex, and the migraine drugs Axert and Maxalt. Our team's pharmaceutical experience in clinical development, sales, marketing and reimbursement, and its medical device experience in research, development and regulatory affairs, allow us to pursue our strategy and growth plans.

230. Amato, Vraniak, Posner, and J. Errico repeatedly admitted to having knowledge of electroCore's business through their public statements. For example:

- So where are we with the commercial payers and PBMs? Currently we have multiple reimbursement agreements in place. The first of which is the CVS Caremark agreement, which will go into effect on January 1, 2019. Under this agreement, we have been advised that approximately 30 million of the 65 million U.S. individuals managed by CVS Caremark will have access to our therapy as a Tier 3 product beginning in January of 2019. Potential access to the remaining 35 million lives will be gained through continuing negotiations with the payers within the CVS network. *Amato*, *Third Quarter 2018 Earnings Conference Call*.
- As Frank noted earlier, the majority of gammaCore prescriptions during the quarter were dispensed under promotional programs. As a result, we're proud to report that we've delivered an additional \$1.7 million of product sales value of gammaCore therapy to patients through our promotional programs. ... This includes vouchers or free therapy and co-pay assistance. Through our co-pay assistance program, we assist patients who have obtained commercial coverage with up to \$100 of their co-pay at the time that gammaCore dispensed. We continue to believe these programs are accomplishing our objectives of providing patient therapy at no charge, demonstrating the benefits of gammaCore therapy to physicians who write prescriptions and promoting U.S. commercial payer coverage and coverage discussions as a result of patient and physician demand. Vraniak, Fourth Quarter 2018 Earnings Conference Call.
- Due largely to the timing of new coverage decision, on the part of CVS Caremark, the Federal Supply schedule and others that commence reimbursement in the first quarter of 2019 as well as continued growth in unique prescribers and the ongoing conversion of promotional scripts to be reimbursed, we continue to anticipate that revenue for 2019 we'll be back-end weighted. *Posner, First Quarter 2019 Earnings Conference Call.*
- As we've shared before, medical researchers the world over are busy studying vagus nerve stimulation for a variety of elements. This interest is the result of the ever growing body of scientific research demonstrating the potent effects of VNS, neurotransmitters, inflammatory mediators, metabolic signaling proteins and even on clotting factors. Translating this potential into the clinic and into commercial success ultimately requires payer reimbursement approval. And payers demand evidence based clinical presentations supported by peer reviewed publications. Fortunately, published clinical data is the cornerstone of our payer outreach efforts and in furtherance of this, I'd like to highlight one paper we recently announced that was published in the highly regarded Journal of the Headache and Pain, which is a retrospective study of chronic and episodic cluster patients who were using gammaCore for at least three to six months. ... On the clinical front, we are working hard to follow up our third label claim, which we received this past year for the prevention of cluster headache. With the clinical data to getting clearance for the potential label claim for the prevention of migraines. To this end, we are in ongoing discussions with FDA

around an application that we plan to submit to support this label. Providing additional support for that indication will be our PREMIUM II trial, which is designed to extend the findings from our prior PREMIUM I trial. It will enroll up to 500 patients in 35 sites across the United States and it began enrollment in the fourth quarter of last year. ... Yes, Marie, this is J.P. The answer to that question is at the present time, it appears to be around 30% to 35%, but it's growing and it's growing rather significantly. We believe that the reason for that is because as the payers come online, the cost or outlay that the patient has to take on in order to remain on therapy is reduced. And so as a result, we saw 300% increases, as Frank mentioned, quarter-over-quarter from third to fourth quarter in refills and we expect and anticipate that to continue to grow into the first quarter and so, I would caution taking anything that I'm saying right now as what it's going to be going forward, because these numbers continue to grow. *J. Errico, Fourth Quarter 2018 Earnings Conference Call*.

- 231. Further, Amato, Vraniak, and Posner signed the SOX certifications for the Forms 10-K and 10-Q filed during the Class Period attesting that the information contained in the 2018 Form 10-K "fairly presents, in all material respects, the financial condition and results of operations of the Company."
- 232. By virtue of their executive and/or directorship positions within a small Company, where gammaCore was the sole product and source of income, and the admitted knowledge above, the Exchange Act Defendants knew, or were reckless in not knowing, non-public material facts concerning gammaCore.

3. <u>Internal Meetings and Reports</u>

233. As discussed in ¶¶ 77, 81, 83, 92, 96, 113 above, the Individual Defendants had access to certain reports and/or were involved in either regular Company meetings or one-on-one meetings where they were updated on crucial information indicating that the statements made herein were materially false and/or misleading and omitted material facts. For example, CW3 provided regular updates to defendant Amato regarding CW3's efforts with commercial payers. CW3 also discussed the code eligibility issue with Amato during in-person meetings. CW7 learned details of the CVS agreement during regular monthly meetings which were attended by defendants

Amato and Vraniak. CW5 stated that there were senior manager meetings twice a month where the Company's efforts to reach agreements with insurance companies were discussed. And, there were quarterly national sales conference calls led by Duhart who reported to Amato, and which Amato occasionally participated in, according to CW6, where updates on the Company's efforts to reach agreements with insurance companies were provided.

- 234. In addition, CW5 stated that defendant Amato received updates from all functional groups at the Company, *i.e.*, Commercial, Sales, Clinical Supply/Device Supply, and Clinical Operations, during the senior manager meetings that took place twice a month in the conference room on the second floor of the Basking Ridge building. CW5 attended those meetings prior to the May 2019 layoffs. According to CW5, Liebler also met weekly with Amato in Amato's office.
- 235. CW6 recalled that Asembia (electroCore's distributor) had a portal showing the number of vouchers submitted for gammaCore, the dates on which prescriptions were written, and status updates for coverage requests. Thus the Exchange Act Defendants would have had access to this information.
- 236. CW7 had frequent in-person conversations with Liebler regarding the trial and met once a week in the conference room to discuss trial updates as well. During the weekly meetings, one of them would type minutes which were then stored on the internal Company database in a Google document. CW7 stated that Liebler would also present updates on the trial to electroCore's senior management and Board members during weekly meetings that were attended by defendants Amato, Vraniak, and J. Errico, among others. Lieber also provided updates about his communications with the FDA during the regular senior leader meetings.
- 237. CW8 stated that the VP of Payer and Provider Strategies spoke with Amato daily and CW8 attended team meetings with Amato and the VP of Payer and Provider Strategies.

"[Amato] had absolute visibility" about the importance of getting coverage for gammaCore and about "everything going on" with electroCore's efforts to reach agreements with payers, said CW8.

- 238. In addition to Amato, Posner and Vraniak knowing that electroCore did not have agreements with insurance companies, CW3 stated that defendants J. Errico, Cox, and Ondra knew as well: "Posner would have definitely known because I know [my successor] spent quite a bit of time speaking with him. Frank [Amato] knew for certain. J.P. Errico knew for certain. Glenn [Vraniak] would have known that." As for defendant Cox, CW3 explained that Duhart had suggested that the Company use a connection Cox had at United Healthcare and CW3 "was on that conference call when we were discussing putting together an agreement [that never materialized] and so forth. So she obviously knew about it." As for Ondra, CW3 explained that since Ondra had worked for one of the Blue Cross organizations "when we were going to present to them, we did a dry run with him and so forth. Then we got the word they weren't going to cover it. We reached out to him to see if he could find out anything else for us. So Stephen Ondra definitely knew." Also, as noted in ¶ 92, CW3's successor told the Board that electroCore did not have any coverage.
- 239. Last, according to CW3, when Duhart asked Amato in early 2019 for more sales representatives to commercialize gammaCore, Amato told him, "We don't have any business. We're not generating revenue with the reps we have. We need to cut back."

4. <u>Substantial Insider Holdings</u>

240. Exchange Act defendants J. Errico, T. Errico, Colucci, Rubin, Tullis, and Amato each had substantial investments and holdings in electroCore, directly or indirectly. For example, according to the Offering Documents, from March 28, 2013 through September 2016, the Company received net proceeds of \$50.7 million from the sale of Series A Preferred Units at initial and later closings and from the conversion of certain loan amounts and exercise of certain related

warrants. Investors in the Series A Preferred Unit financings, directly or indirectly, included defendants J. Errico, T. Errico, Colucci, GHI (which Rubin served as a Managing Director of), and Tullis.

- 241. In addition, from September 2016 through June 2017, the Company raised approximately \$25.6 million from Bridge notes and issued approximately 41.9 million common units to the bridge investors. CV II, which T. Errico and J. Errico are managing directors of, purchased approximately \$16.9 million in Bridge notes and was issued approximately 33.7 million common units. This was later converted at the initial Series B closing below.
- 242. In July 2017, CV II, GHI, Tullis and Tullis Opportunity Fund II (an entity for which defendant Tullis serves as the managing partner of its general partner), entered into a commitment letter with electroCore pursuant to which they agreed to invest in the aggregate approximately \$9.0 in initial closing of the Company's Series B Preferred Unit financing. The specific commitment amounts are as follows: GHI \$5 million; CV II \$3.87 million; Tullis and Tullis Opportunity Fund II \$300,000. The initial Series B closing was consummated in August 2017 with those amounts, plus \$990,463 invested by ECNG, LLC, a limited liability company in which T. Errico and J. Errico also have a pecuniary interest. In additional Series B closings from September through December 2017, CV II invested an additional \$8.4 million.
- 243. After the IPO, according to the Offering Documents, CV II beneficially owned 26.7% of electroCore's common stock; CV IV owned 4.9%, GHI owned 10.5%; Amato owned 1.2%; J. Errico owned 43%; and T. Errico owned 42%.

5. <u>Insider Sales</u>

244. While in possession of material, nonpublic information regarding gammaCore's insurance reimbursement issues, among other things, defendant J. Errico sold 100,000 shares of electroCore stock during the Class Period reaping net proceeds of \$566,634.04, as illustrated in

the table below. J. Errico had not sold any shares of electroCore prior to his first Class Period sale on January 15, 2019. Thus, J. Errico was highly motivated to engage in the alleged fraudulent scheme and issue materially false and misleading statements and/or omit material facts in order to inflate electroCore's securities price and maximize individual profits.

Date	No. Shares	Price Per	Proceeds
	Sold ⁷	Share	
1/15/2019	22,349	\$4.90	\$109,510.10
1/16/2019	19,810	\$4.89	\$96,870.90
1/17/2019	7,841	\$4.84	\$69,314.44
4/01/2019	10,408	\$6.97	\$72,543.76
4/11/2019	13,723	\$5.49	\$75,339.27
4/12/2019	25,869	\$5.53	\$143,055.57
Total	100,000		\$566,634.04

245. Indeed, J. Errico's Class Period sales did not go unnoticed. On the May 14, 2019 first quarter 2019 earnings call, an analyst from Evercore ISI raised the issue of J. Errico's sales:

And then last question I have to ask because a few investors have expressed dismay over JP [Errico] initiating stocks don't plan at the time of the stock is so far below the IPO price. So perhaps, you can address why you felt that this prudent timing, considering the poor optics and why we shouldn't take that as a lack of confidence and the outlook for the Company at the current valuation?

E. Loss Causation

246. During the Class Period, as detailed herein, the Exchange Act Defendants engaged in a fraudulent scheme to deceive the market that artificially inflated the price of electroCore securities and operated as a fraud or deceit on Class Period purchasers of electroCore securities.

247. The Exchange Act Defendants' materially false and/or misleading statements and omissions concealed, *inter alia*, that: (i) the type and size of third-party payer agreements purportedly in place were substantially different then represented; (ii) the PBM agreements included material adverse limitations on coverage and reimbursement; (iii) due to the uniqueness

⁷ While the shares sold were pursuant to a 10b5-1 plan, the plan was entered into during the Class Period.

of gammaCore, the Company faced substantial undisclosed issues preventing payer coverage; (iv) electroCore's voucher program was harming the Company's negotiations with payers; and, (v) the foregoing would require significant cash outlays, accelerating cash burn and making the Company's purported business strategies unattainable. As detailed above, when the truth was revealed, the price of electroCore's securities declined significantly as the prior artificial inflation was removed from the Company's stock price.

- 248. As a result of their purchases of electroCore's securities during the Class Period, at artificially inflated prices, Lead Plaintiff and the Class suffered damages under the federal securities laws.
- 249. The artificial inflation created by the Exchange Act Defendants' misrepresentations and omissions was partially removed in a series of disclosures as follows:
 - (i) On May 14, 2019, the Company announced dismissal earnings and stated, among other things, that (i) the CVS agreement would only cover gammaCore for patients after they had tried three other medications; and (ii) a universal diagnostic code for gammaCore had only just been instituted.

 See ¶¶ 200-205. Following these disclosures, electroCore's share price declined by \$1.58 per share, over 29%, on heavier than usual trading volume, to close on May 15, 2019 at \$3.75 per share.
 - (ii) On May 29, 2019, electroCore announced a comprehensive redeployment and cost reduction plan, including scaling back its clinical development program, one of the purported key business strategies for the Company as gammaCore's approved uses served only a small subset of the headache population. On this news, electroCore's share price fell \$0.11, or over 5%,

- to close at \$1.95 per share on May 30, 2019 on unusually heavy trading volume. electroCore's share price continued to drop over the next two trading days on heavier than usual trading volume to finally close at \$1.65 per share on June 3, 2019, an overall decrease of over 15%.
- (iii) On August 13, 2019, the Company disclosed restructuring charges associated with the comprehensive deployment and cost reduction plan and announced an expected quarterly cash burn of over \$7 million. Following these disclosures, electroCore's share price fell \$0.17 per share, or over 10%, on unusually heavy trading volume, from a closing price per share of \$1.56 on August 13, 2019 to a closing price per share of \$1.39 on August 14, 2019.
- (iv) On September 25, 2019, it was revealed that the FDA had requested more information and analysis of clinical data for the Company's 510(k) submission for expansion of use for gammaCore. On this news, electroCore's share price fell \$0.79 per share, or 23%, on unusually heavy trading volume, to close at \$2.57 per share on September 25, 2019.
- 250. The timing and magnitude of the price decline in electroCore's stock on the date of each disclosure above negates any inference that the losses suffered by Lead Plaintiff and the Class were caused by changed market conditions, macroeconomic or industry facts, or Company-specific facts unrelated to the Exchange Act Defendants' fraudulent conduct.
- 251. The damages suffered by Lead Plaintiff and the Class were the direct and proximate result of the Exchange Act Defendants' materially false and misleading statements and omissions that artificially inflated the Company's stock price and the subsequent significant decline in the

value of the Company's stock when the truth concerning the Exchange Act Defendants' prior misrepresentations and fraudulent conduct were revealed.

F. No Safe Harbor

- 252. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the statements alleged to be false and/or misleading herein. The statements alleged herein all relate to then-existing facts and conditions.
- 253. To the extent that statements alleged to be false and/or misleading are characterized as forward-looking, the statutory safe harbor does not apply to such statements because they were not sufficiently identified as "forward-looking statements" when made, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements, and the Exchange Act Defendants had actual knowledge that the forward-looking statements were materially false or misleading at the time each such statement was made.

G. Presumption of Reliance; Fraud-on-the-Market

- 254. The market for electroCore securities was open, well-developed, and efficient at all relevant times. As a result of the Exchange Act Defendants' materially false and/or misleading statements and material omissions, electroCore securities traded at artificially inflated prices during the Class Period. Lead Plaintiff and the Class purchased or otherwise acquired the Company's securities relying on the integrity of the market price of such securities and on publicly available market information relating to electroCore, and have been damaged thereby.
- 255. During the Class Period, the artificial inflation of the value of electroCore's stock was caused by the material misrepresentations and omissions particularized in this Complaint, thereby causing the damages sustained by Lead Plaintiff and the Class. As described herein, during the Class Period, the Exchange Act Defendants made or caused to be made a series of materially

false or misleading statements about the Company's business, prospects, and operations, causing the price of the Company's stock to be artificially inflated at all relevant times. When the truth was disclosed, it drove down the value of the Company's stock, causing Lead Plaintiff and other Class members that had purchased the stock at artificially inflated prices to be damaged as a result.

- 256. Lead Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:
 - The Exchange Act Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - the omissions and misrepresentations were material;
 - electroCore securities are traded in an efficient market;
 - the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
 - the Company traded on the NASDAQ and was covered by analysts;
 - the misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
 - Lead Plaintiff and members of the Class purchased, acquired, and/or sold electroCore securities between the time the Exchange Act Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 257. Based upon the foregoing, Lead Plaintiff and the Class are entitled to a presumption of reliance upon the integrity of the market.
- 258. Alternatively, Lead Plaintiff and the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as the Exchange Act Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

H. Causes of Action Under Sections 10(b) and 20(a) of the Exchange Act

COUNT IV

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 (Against All Exchange Act Defendants)

- 259. Lead Plaintiff repeats and re-alleges each and every allegation above as if fully set forth herein.
- 260. This Count is asserted against electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by the SEC.
- 261. During the Class Period, the Exchange Act Defendants carried out a plan, scheme, and course of conduct, which was intended to, and throughout the Class Period, did: (i) deceive the investing public, including Lead Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of electroCore securities; and (iii) cause Lead Plaintiff and other members of the Class to purchase or otherwise acquire electroCore securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Exchange Act Defendants, and each of them, took the actions set forth herein.
- 262. The Exchange Act Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period in an effort to maintain artificially high market prices for electroCore's securities in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.
- 263. The Exchange Act Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, engaged and

participated in a continuous course of conduct to conceal and misrepresent adverse material information about the Company's business, operations, and financial results, as specified herein.

- 264. Pursuant to the above plan, scheme, and course of conduct, each of the Exchange Act Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for electroCore securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented electroCore's true condition.
- 265. The Company and the Individual Defendants named in this Count had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Lead Plaintiff and the other members of the Class, or, in the alternative, the Exchange Act Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to these defendants. Said acts and omissions of the Exchange Act Defendants were committed willfully or with reckless disregard for the truth. In addition, each Exchange Act Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.
- 266. Information showing that the Exchange Act Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Exchange Act Defendants' knowledge and control. As senior officers and directors of electroCore, the Individual Defendants named herein had knowledge of the details of electroCore's internal affairs.

- 267. The Individual Defendants named herein are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, these defendants were able to and did, directly or indirectly, control the content of the statements of electroCore. As senior officers and/or directors of a publicly-held company, the Individual Defendants named herein had a duty to disseminate timely, accurate, and truthful information with respect to electroCore's businesses, operations, financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of electroCore securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning electroCore's business and financial condition which were concealed by the Exchange Act Defendants, Lead Plaintiff and the other Class members purchased or otherwise acquired electroCore securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by the Exchange Act Defendants, and were damaged thereby.
- 268. During the Class Period, electroCore securities were traded on an active and efficient market. Lead Plaintiff and the Class, relying on the materially false and misleading statements described herein, which the Exchange Act Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased, or otherwise acquired shares of electroCore securities at prices artificially inflated by the Exchange Act Defendants' wrongful conduct. Had Lead Plaintiff and the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Lead Plaintiff and the Class, the true value of electroCore securities was substantially lower than the prices paid

by Lead Plaintiff and the Class. The market price of electroCore securities declined sharply upon public disclosure of the facts alleged herein to the injury of Lead Plaintiff and the Class.

- 269. By reason of the conduct alleged herein, the Exchange Act Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and SEC Rule 10b-5.
- 270. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Lead Plaintiff and the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating material misrepresentations to the investing public.

COUNT V

For Violations of Section 20(a) of the Exchange Act (Against Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis)

- 271. Lead Plaintiff repeats and re-alleges each and every allegation above as if fully set forth herein.
- 272. During the Class Period, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis participated in the operation and management of electroCore, and conducted and participated, directly and indirectly, in the conduct of electroCore's business affairs. Because of their senior positions and/or directorships, they knew the adverse non-public information about electroCore's misstatements regarding gammaCore and the Company's business.
- 273. As officers and/or directors of a publicly owned company, these defendants had a duty to disseminate accurate and truthful information with respect to electroCore and its flagship

product, and to correct promptly any public statements issued by electroCore which had become materially false or misleading.

- 274. Because of their positions of control and authority as senior officers and/or directors, these defendants were able to and did control the contents of the various reports, press releases and public filings which electroCore disseminated in the marketplace during the Class Period. Throughout the Class Period, these defendants exercised their power and authority to cause electroCore to engage in the wrongful acts complained of herein. These Individual Defendants named herein, therefore, were "controlling persons" of electroCore within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of electroCore securities.
- 275. Each of the Individual Defendants named herein, therefore, acted as a controlling person of electroCore. By reason of their senior management positions and/or being directors of electroCore, each of these defendants had the power to direct the actions of, and exercised the same to cause, electroCore to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants named in this Count exercised control over the general operations of electroCore and possessed the power to control the specific activities which comprise the primary violations about which Lead Plaintiff and the other members of the Class complain.
- 276. By reason of the above conduct, the Individual Defendants named in this Count are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by electroCore.

VIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and certifying Lead Plaintiff as the Class Representative;

- B. Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial;
- C. Awarding Lead Plaintiff and the members of the Class rescission, disgorgement, and all other remedies in equity or in law pursuant to the Securities Act;
- D. Awarding Lead Plaintiff and the other members of the Class prejudgment and postjudgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and
 - E. Awarding such other and further relief as this Court may deem just and proper.

IX. DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: October 4, 2021 Respectfully submitted,

BRAGAR EAGEL & SQUIRE, P.C.

/s/ Lawrence P. Eagel

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